

EXHIBIT D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

3 IN RE: ETHICON, : Master File No.
4 INC. PELVIC : 2:12-MD-02347
5 REPAIR SYSTEM : MDL No. 2327
6 PRODUCTS :
7 LIABILITY : Joseph R. Goodwin
8 LITIGATION : U.S. District Judge
9 ----- :
10 ROSE GOMEZ, et al :
11 Case no. :
12 2:12-CV-00344 :

13 - - -

14 Thursday, March 31, 2016

15 - - -

16 Oral deposition of JULIE DROLET, M.D.,
17 taken pursuant to notice, at the Courtyard
18 by Marriott York, 2799 Concord Road, York,
19 Pennsylvania, commencing on the above date
20 at or about 1:28 p.m., before Eileen P.
21 Barth, C.S.R., N.P.

22 - - -

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Julie Drolet, M.D.

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2
3 DIRECTIONS NOT TO ANSWER
4 PAGES: None
5 REQUESTS FOR DOCUMENTS OR INFORMATION
6 PAGES: None
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8 STIPULATIONS AND/OR STATEMENTS:
9 PAGES: None
10 MARKED QUESTIONS:
11 PAGES: None
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1 JULIE DROLET, M.D., having
2 been duly sworn, was examined and
3 testified as follows:
4 BY MR. ZONIES:
5 Q. Good afternoon, Doctor
6 Drolet. How are you?
7 A. I'm fine. Thank you.
8 Q. We just finished up the
9 deposition the Prolift+M; is that right?
10 A. That is correct.
11 Q. And to the extent that our
12 conversations about the reliance
13 materials and Exhibits 1 and 2 and 3 and
14 the thumb drive that you brought with you
15 today, to the extent that we discuss
16 those things, I'll incorporate those into
17 this deposition so we don't have to do it
18 again. Is that okay with you?
19 A. For the most part I guess.
20 Q. Is there some part that
21 isn't?
22 A. I don't know. It depends on
23 your questions. I reserve the right to
24 change or to add.

<p style="text-align: right;">Page 6</p> <p>1 Q. And is there anything over 2 the lunch hour that you would like to 3 change or add from our discussions this 4 morning? 5 A. I didn't think about this 6 case over the lunch hour. 7 Q. So as you sit here right 8 now, the answer is no, there's nothing to 9 change or add? 10 A. At this point in time. 11 Q. Thank you. 12 Doctor, this deposition is 13 about the TVT-O device. Do you have that 14 understanding? 15 A. I do. 16 Q. And you issued an expert 17 report about the TVT-O device; correct? 18 A. I issued an expert report on 19 the Gomez case that included my opinion 20 on the TVT-O device. 21 Q. Doctor, when did you first 22 use a synthetic sling device for 23 treatment of stress urinary incontinence? 24 A. 2002.</p>	<p style="text-align: right;">Page 8</p> <p>1 urinary incontinence, yes. 2 Q. What procedures? 3 A. Those were transvaginal 4 using the vaginal mucosa as a sling with 5 sutures, polypropylene sutures, sorry, 6 prolene sutures. 7 Q. And what are those? Is 8 there a name for these surgeries? 9 A. They're considered part of 10 the bladder neck sling group or 11 pubovaginal sling group. 12 Q. And when did you perform 13 those? 14 A. Before 2002. 15 Q. Did you stop doing 16 pubovaginal slings when you started to 17 use the TVT Retropubic? 18 A. Yes, I had. 19 Q. Have you done any since 20 2002? 21 A. Not that I can recall. 22 Q. Have you ever done a Burch 23 procedure? 24 A. Yes.</p>
<p style="text-align: right;">Page 7</p> <p>1 Q. And what device did you use 2 in 2002? 3 A. It was the Gynecare TVT. 4 Q. Is that also known as the 5 TVT Retropubic? 6 A. Yes, it is. 7 Q. And that's a retropubic 8 package to implant the mesh; correct? 9 A. That it is. 10 Q. How long did you use the TVT 11 Retropubic device? 12 A. For a few years. I am still 13 doing retropubic approaches but now doing 14 transobturator approaches as well. 15 Q. And after starting with the 16 TVT Retropubic, what was the next sling 17 that you used? 18 A. I don't recall specifically. 19 Q. Have you ever done any 20 nonsynthetic sling procedures? 21 A. Yes. 22 Q. For treatment of stress 23 urinary incontinence? 24 A. For treatment of stress</p>	<p style="text-align: right;">Page 9</p> <p>1 Q. How many times? 2 A. Hundreds. 3 Q. When was the last time you 4 did a Burch? 5 A. A few months ago. 6 Q. You continue to do Burch 7 procedures at this point in your career? 8 A. Yes. Not as frequently. 9 Q. I'm sorry? 10 A. Not as frequently since the 11 slings have appeared. The midurethral 12 slings. Pardon me. 13 Q. From 2002 when you first 14 started to use synthetic slings until 15 today in 2016, have you continuously also 16 done Burch procedures during that period 17 of time? 18 A. Yes. 19 Q. Any other procedures that 20 you have used for the treatment of stress 21 urinary incontinence? 22 A. For the treatment of stress 23 incontinence? No, not for the treatment. 24 Q. Have you ever used bulking</p>

<p style="text-align: right;">Page 10</p> <p>1 agents?</p> <p>2 A. I was trained on them, but</p> <p>3 no.</p> <p>4 Q. Why not?</p> <p>5 A. At the hospital where I</p> <p>6 practice, there's a territorial issue</p> <p>7 between the urologists and I as a female</p> <p>8 urogynecologist and so it was something</p> <p>9 that I decided that politically I would</p> <p>10 pick my battles, so I don't have</p> <p>11 experience with bulking agents.</p> <p>12 Q. You said at some point you</p> <p>13 did do them in your training was it?</p> <p>14 A. Yes. I went to a training</p> <p>15 session for bulking agents.</p> <p>16 Q. When was that?</p> <p>17 A. 2010 or 2011. I can't</p> <p>18 remember exactly.</p> <p>19 Q. Did you find during that</p> <p>20 training session that the bulking agents</p> <p>21 were effective for the treatment of</p> <p>22 stress urinary incontinence?</p> <p>23 A. This was a training session</p> <p>24 with pelvic models and cadavers, so I</p>	<p style="text-align: right;">Page 12</p> <p>1 be an appropriate treatment, you would</p> <p>2 refer that patient to this other</p> <p>3 physician?</p> <p>4 A. Absolutely.</p> <p>5 Q. And what is his or her name?</p> <p>6 A. Doctor Sisbarro.</p> <p>7 Q. How do you spell that?</p> <p>8 A. S-I-S-B-A-R-R-O.</p> <p>9 Q. And do you have a financial</p> <p>10 arrangement with Doctor Sisbarro?</p> <p>11 A. Absolutely not.</p> <p>12 Q. And is it your understanding</p> <p>13 that when Doctor Sisbarro has a patient</p> <p>14 where he believes it might be appropriate</p> <p>15 that that patient have a surgical</p> <p>16 procedure aside from bulking agents to</p> <p>17 treat stress urinary incontinence he</p> <p>18 would refer that patient to you?</p> <p>19 A. I don't know if that's</p> <p>20 happened for stress urinary incontinence.</p> <p>21 Q. For other laparoscopic</p> <p>22 surgeries however it happens?</p> <p>23 A. He has sent me patients who</p> <p>24 were in need of prolapse, pelvic organ</p>
<p style="text-align: right;">Page 11</p> <p>1 couldn't establish the effectiveness</p> <p>2 since pelvic models and cadavers don't</p> <p>3 leak.</p> <p>4 Q. Who sponsored that training</p> <p>5 session?</p> <p>6 A. I think it was Coloplast.</p> <p>7 They make Durasphere.</p> <p>8 Q. If you didn't have these</p> <p>9 political concerns that you discussed,</p> <p>10 are bulking agents something that you</p> <p>11 would consider bringing into your</p> <p>12 armament to fight stress urinary</p> <p>13 incontinence for your patients?</p> <p>14 A. At this point in my career,</p> <p>15 possibly not.</p> <p>16 Q. Why not?</p> <p>17 A. Because I have a new great</p> <p>18 urologist co-worker who does a lot and we</p> <p>19 compliment each other. He doesn't do</p> <p>20 laparoscopy, doesn't do laparoscopic</p> <p>21 Burch, I do, and so we have a very good</p> <p>22 working relationship.</p> <p>23 Q. So if you believe and a</p> <p>24 patient agrees that a bulking agent might</p>	<p style="text-align: right;">Page 13</p> <p>1 prolapse care, and so he has referred</p> <p>2 them to me. I've referred more to him</p> <p>3 than he to me.</p> <p>4 Q. It always works that way.</p> <p>5 A. It's fine. It's all good.</p> <p>6 Q. Do you find the Burch -- you</p> <p>7 do the Burch procedure laparoscopically?</p> <p>8 A. Most of them, yes.</p> <p>9 Q. You've done some laparotomy</p> <p>10 however?</p> <p>11 A. Open, yes.</p> <p>12 Q. Do you find that to be a</p> <p>13 safe and effective procedure?</p> <p>14 A. I do.</p> <p>15 Q. The Burch has been described</p> <p>16 historically as a gold standard</p> <p>17 treatment. Do you agree that it is</p> <p>18 indeed a gold standard treatment?</p> <p>19 A. I agree that it has been</p> <p>20 described as a gold standard treatment.</p> <p>21 Q. And in 2002 you started to</p> <p>22 use a TVT Retropubic. When do you think</p> <p>23 you introduced another synthetic sling</p> <p>24 into your practice?</p>

<p style="text-align: right;">Page 14</p> <p>1 A. I can't recall exactly.</p> <p>2 Q. Today in your practice do</p> <p>3 you continue to use synthetic slings?</p> <p>4 A. I do.</p> <p>5 Q. Which slings do you use</p> <p>6 today?</p> <p>7 A. Today I use the Coloplast</p> <p>8 T-Sling, retropubic and transobturator.</p> <p>9 Q. Is that the only one you use</p> <p>10 now?</p> <p>11 A. Today, yes.</p> <p>12 Q. When did you start using the</p> <p>13 Coloplast T-Sling?</p> <p>14 A. Oh, many years ago.</p> <p>15 Whenever the Coloplast mesh we used was</p> <p>16 bought out by Coloplast, so many years</p> <p>17 ago.</p> <p>18 Q. Was that about the same time</p> <p>19 that you switched over to using</p> <p>20 Coloplast's pelvic floor mesh as well?</p> <p>21 Restorelle?</p> <p>22 A. I'm trying to think. I</p> <p>23 think I was using the T-Sling before.</p> <p>24 Yeah, a few years before.</p>	<p style="text-align: right;">Page 16</p> <p>1 Okay?</p> <p>2 A. Retropubic.</p> <p>3 Q. Yes.</p> <p>4 A. Down up and not top down.</p> <p>5 Q. Correct.</p> <p>6 A. Okay.</p> <p>7 Q. All right? So what's</p> <p>8 sometimes known in our circles as the TVT</p> <p>9 classic, the original TVT device designed</p> <p>10 by --</p> <p>11 A. Ulmsten.</p> <p>12 Q. Correct. So the Ulmsten</p> <p>13 device, the TVT Retropubic, you would</p> <p>14 have stopped using that device at about</p> <p>15 the time that you started to use either</p> <p>16 the Caldera or Coloplast T-Sling; is that</p> <p>17 right?</p> <p>18 A. That sounds about right.</p> <p>19 Q. And it sounds like that may</p> <p>20 have been around or earlier than 2010; is</p> <p>21 that fair?</p> <p>22 A. It's possible, but I cannot</p> <p>23 give you an exact date without getting</p> <p>24 all hospital records and going back to</p>
<p style="text-align: right;">Page 15</p> <p>1 Q. Before you started to use</p> <p>2 Restorelle?</p> <p>3 A. Yes. I think so.</p> <p>4 Q. Does it help at all to say</p> <p>5 that may have been around 2010 or '11?</p> <p>6 A. The Restorelle was around</p> <p>7 2010, 2011. The T-Sling was probably</p> <p>8 before that. It might have been called</p> <p>9 Caldera. So different.</p> <p>10 Q. Different manufacturer?</p> <p>11 A. Yes.</p> <p>12 Q. But the same product?</p> <p>13 A. From what was reported to</p> <p>14 me.</p> <p>15 Q. Understood. When you</p> <p>16 started to use the T-Sling, did you stop</p> <p>17 using the TVT Retropubic?</p> <p>18 A. Yes. The Gynecare</p> <p>19 Retropubic.</p> <p>20 Q. Yes. And to be clear, I</p> <p>21 understand that sometimes TVT is like</p> <p>22 Frisbee. It's a generic term for a</p> <p>23 device. But when I use the phrase TVT,</p> <p>24 I'm talking about Ethicon's TVT products.</p>	<p style="text-align: right;">Page 17</p> <p>1 all patients.</p> <p>2 Q. So at one point earlier when</p> <p>3 we were discussing the Prolift+M, you</p> <p>4 said that you had one of your office</p> <p>5 workers go through and do sort of an</p> <p>6 analysis of how many Prolifts and</p> <p>7 Prolift+Ms you had implanted in the</p> <p>8 timeframe from 2005 I think it was to</p> <p>9 2015. Do you recall saying that?</p> <p>10 MS. GRAFF: Object to form.</p> <p>11 THE WITNESS: I recall</p> <p>12 talking about that, yes.</p> <p>13 BY MR. ZONIES:</p> <p>14 Q. Roughly? Did you also at</p> <p>15 that time look at which slings you had</p> <p>16 implanted and how many?</p> <p>17 A. How many? Yes. The type of</p> <p>18 sling and the root of approach was not</p> <p>19 specified.</p> <p>20 Q. So first can you tell me how</p> <p>21 many slings you believe you have used for</p> <p>22 the treatment of stress urinary</p> <p>23 incontinence in women?</p> <p>24 A. As far as midurethral</p>

<p style="text-align: right;">Page 18</p> <p>1 slings, up until October of 2015 I think 2 the count was 350, 351. Since that time 3 maybe 15, 20 more, 15, more. That makes 4 sense. 5 Q. I'm sorry. Could you just 6 repeat those numbers so I can write them 7 down? You said from -- 8 A. From -- 9 Q. Is this from 2002 or do you 10 think this is also from 2005? 11 A. 2005. 12 Q. 2005? 13 A. 2005, pardon me, because our 14 records don't go back that far. 15 Q. So from 2005 until when you 16 had the count done in October of 2015 it 17 was approximately how many slings? 18 A. 351 or 357. I can't 19 remember. 20 Q. And then from that October 21 2015 until today in March? 22 A. Another 15 would 23 statistically make sense as well. 24 Q. What do you mean by</p>	<p style="text-align: right;">Page 20</p> <p>1 mini slings that you've tried? The Bard 2 and TVT-S? 3 A. Yes. 4 Q. Yes? 5 A. Yes. The two types of mini 6 slings are, I think it's called Bard, 7 it's Ajust, and the other one was a TVT 8 Secur that I tried when mini slings 9 became more popular and I'm still using 10 the T-Sling for now. 11 Q. So when do you believe you 12 first used or tried the TVT Obturator by 13 Ethicon? 14 A. I can't recall exactly. 15 Q. And when you began to use 16 the T-Sling by Caldera or Coloplast, you 17 said earlier that you stopped using the 18 TVT Retropubic from Ethicon; correct? 19 A. That would be correct. 20 Q. And because the T-Sling has 21 either approach, obturator or retropubic, 22 when you started to use the T-Sling, did 23 you also stop using the TVT Obturator 24 from Ethicon?</p>
<p style="text-align: right;">Page 19</p> <p>1 "statistically make sense"? 2 A. If I do an average of 30 or 3 31, 32 a year for ten years between 2005, 4 2015, from October to March, that's six 5 months, makes sense. That's why I added 6 roughly 15 to the count. 7 Q. That's about the pace at 8 which you feel that -- that's about the 9 pace at which your data showed that you 10 used these was roughly 30 per year? 11 A. Yes. 12 Q. So we've talked about the 13 TVT Retropubic, the Ulmsten device and 14 we've talked about the T-Sling. Were 15 there any other midurethral slings that 16 you've used in your practice? 17 A. Yes. I have tried two mini 18 slings. 19 Q. Which two? 20 A. I think one was called the 21 Bard Ajust, I have done the TVT-O, I have 22 done -- one of the hospitals in town uses 23 Obtryx, I have tried two TVT Securs. 24 Q. Is that included in the two</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Yes. 2 Q. So if we can determine when 3 you started to use the T-Sling, we know 4 that that's the cutoff, that's the last 5 time you had used a TVT Retropubic, a TVT 6 Obturator and you've only used the TVT 7 Secur for two surgeries? Is that a fair 8 assessment of your TVT sling use? 9 A. Not exactly because I can't 10 coincide a hundred percent going from 11 retropubic, Gynecare products to another 12 product, two those, TVT and TVT-O versus 13 the Caldera or Coloplast product, that 14 may not have been a complete cut. I'm 15 not quite sure which one happened first, 16 did they both coincide. I'm not quite 17 sure. 18 Q. But that overlap would be -- 19 in other words, if you stopped using the 20 TVT Retropubic the day you started to use 21 the T-Sling, you may have continued to 22 use the TVT Obturator for a few weeks or 23 a few months after starting to use the 24 T-Sling?</p>

Page 22

1 A. That is entirely possible,
2 but I cannot recall exactly the dates or
3 the timeframe.
4 Q. And regardless we know that
5 of all the products you did approximately
6 statistically an average of 30 of these
7 midurethral sling procedures per year?
8 A. That's what I counted, yes.
9 Q. And then how many Burchs do
10 you believe you've done from 2005 to the
11 present day?
12 A. Those were not counted. I
13 would imagine that I did very few of
14 them. The ones that I did would have
15 been associated with a sacrocolpopexy or
16 for other indications.
17 Q. And how about for
18 pubovaginal slings? Did you do
19 pubovaginal slings during this period of
20 time?
21 A. No.
22 Q. Did you do any sling repairs
23 using native tissue?
24 A. That would be a pubovaginal

Page 23

1 sling. The answer is no.
2 Q. Why not?
3 A. Because the midurethral
4 slings offered good efficacy, good
5 safety, surgical time was greatly
6 reduced, other benefits, complications,
7 you know.
8 Q. But you didn't learn that
9 from your own personal experience because
10 you've never used a pubovaginal native
11 tissue repair; correct?
12 A. Correct I think. Could you
13 repeat that question?
14 Q. Sure. Have you ever used a
15 pubovaginal sling?
16 A. Not in my practice.
17 Q. Just in training?
18 A. Yes.
19 Q. And that was the one time
20 years ago that we discussed; right?
21 A. Now, you'd have to go back
22 and ask me that again.
23 Q. When was that?
24 A. Many years ago.

Page 24

1 Q. Before you were in private
2 practice here in the United States?
3 A. In the United States,
4 correct.
5 Q. And you started your
6 practice here in the United States I
7 think in 1997?
8 A. I arrived here in '97, yes.
9 Q. So you haven't done a
10 pubovaginal sling since before 1997?
11 A. That is correct.
12 Q. Aside from the Burch and the
13 slings, the midurethral slings that we
14 had discussed and the bulking agents, are
15 there any other surgical treatments for
16 stress urinary incontinence in women that
17 you have utilized?
18 A. Yes. You asked me that and
19 I said using the vaginal mucosa as a
20 sling.
21 Q. And when did you do that?
22 A. Before I went for training
23 on the TVT which was in 2002, so sometime
24 before 2002.

Page 25

1 Q. And since 2002 you haven't
2 had the opportunity to use that
3 procedure?
4 A. I haven't done any.
5 Q. And how many did you do?
6 A. I can't recall.
7 Q. What was your experience
8 with the TVT Secur?
9 A. In my hands and at training,
10 I felt that it wasn't a procedure that I
11 can easily teach the residents and I
12 didn't have as much control over, so it
13 wasn't something that I would incorporate
14 in my practice at the teaching hospital
15 or where I do most of my surgical
16 procedures.
17 Q. And you said in your hands
18 at training. What training did you have
19 for the TVT-S?
20 A. I went to I think it was in
21 Allentown but I can't be for sure. Vince
22 Lucente was the trainer and that's as
23 much as I can tell you.
24 Q. And was this an

<p style="text-align: right;">Page 26</p> <p>1 Ethicon-sponsored training that you went 2 to where Doctor Lucente was the trainer? 3 A. I would imagine, but I can't 4 guarantee that a hundred percent that it 5 was. 6 Q. Do you recall were there 7 other doctors there as well as you? 8 A. For the TVT Secur I can't 9 recall. 10 Q. Do you have a sense of when 11 that would have been? 12 A. No. 13 Q. Did you have difficulty 14 using the TVT Secur during the training 15 sessions? 16 A. Not that I -- I wouldn't 17 call it difficulty. To me it was more 18 the fine adjustment when we have to 19 position compared to a traditionally long 20 sling, full length sling, didn't have the 21 ease of adjusting compared to the 22 transobturator or retropubic approach. 23 Q. And by adjusting do you mean 24 adjusting the tensioning on the tape?</p>	<p style="text-align: right;">Page 28</p> <p>1 feel, some people do it visually. 2 Everybody has got their own -- just like 3 pubovaginal slings or Burch. We have to 4 lift the urethral vesicle junction at a 5 certain level on a Burch but it can't be 6 under too much tension. So it's a 7 question of experience and teaching. 8 Everybody does it different. 9 Q. There's no uniform way to 10 describe it? 11 A. We don't have a protractor, 12 an angle measurement or any specific sign 13 that is the guarantee of the perfect 14 positioning and/or tensioning. Just like 15 a lot of surgeries, it goes on 16 experience, training, and every patient 17 is different. 18 Q. I've heard it described as a 19 Goldilocks principle. Do you know what I 20 mean by that? 21 A. Yes, I do. 22 Q. Do you think that that's an 23 accurate description, not too tight, not 24 too loose, just right?</p>
<p style="text-align: right;">Page 27</p> <p>1 A. Or the lack thereof, but 2 adjusting it to where we think it would 3 correct the incontinence and it would 4 rest underneath the midurethra. It's my 5 personal opinion, my personal preference, 6 I would rather do full length slings. 7 Q. How would you describe the 8 tension or lack thereof that you believe 9 is the correct way to perform a 10 midurethral sling? 11 MS. GRAFF: Can I hear that 12 question again? I'm sorry. 13 MR. ZONIES: Sure. 14 BY MR. ZONIES: 15 Q. Can you describe in your own 16 words, Doctor, what tensioning you 17 believe a TVT Obturator should 18 appropriately have? 19 A. Every physician whether it's 20 for retropubic, transobturator, out to 21 in, in to out has their own way and it 22 comes with experience, feeling, some 23 people do a Crede's maneuver, some people 24 have women cough, some people do it by</p>	<p style="text-align: right;">Page 29</p> <p>1 A. Well, I wouldn't use the 2 word Goldilocks in its literal 3 application, but it is something that 4 there's no precise, not too tight and not 5 too loose. 6 Q. It's certainly not 7 tension-free; is that correct? 8 A. I don't know how the initial 9 -- or Professor Ulmsten intended the word 10 tension-free to be and if his definition 11 of tension would be to anchor it via 12 sutures, bone anchors, staples to a 13 particular object to lift the urethra up 14 as we do with pubovaginal slings or 15 Burchs, then this would be tension-free 16 because we're not using those anchors. 17 There's always tension. 18 Q. Yeah, and I suppose -- 19 A. It would fall apart on the 20 floor if there wasn't any tension. 21 Q. I suppose my question is 22 there is tension required for a TVT 23 Obturator to work appropriately? 24 A. The mesh whether it's from</p>

<p style="text-align: right;">Page 30</p> <p>1 retropubic, transobturator, out to in, in 2 to out or TOT, TVT-O has to have some 3 substance to it in order to be a, 4 quote/unquote, backstop to the abdominal 5 pressure when a patient has coughing, 6 sneezing, laughing. That's what we think 7 is the midurethral continence mechanism 8 associated with these types of slings. 9 Q. And to obtain that with a 10 TVT Obturator, it necessarily requires 11 some tension; correct? 12 MS. GRAFF: Object to the 13 form. You can answer. 14 THE WITNESS: It has to stay 15 in place. If it doesn't, then at 16 the first cough then the whole 17 thing would again fall out, so we 18 have to place it in a certain area 19 but not pull or put tension on the 20 urethra, so the tension-free maybe 21 applicable to the midurethra and 22 not the material itself. 23 BY MR. ZONIES: 24 Q. So tension-free might mean</p>	<p style="text-align: right;">Page 32</p> <p>1 form. Now we're back to the TVT 2 Secur? 3 MR. ZONIES: Yes. 4 THE WITNESS: I answer that? 5 MS. GRAFF: If you can. 6 THE WITNESS: Yes, at that 7 time. 8 BY MR. ZONIES: 9 Q. Did you receive a 10 certificate saying that you had completed 11 the training? 12 A. I don't recall. 13 Q. Did you ever, in the 14 training, did you perform any procedures 15 on women? Patients? 16 A. I don't recall specifically. 17 Q. Do you recall was it a 18 cadaver lab? 19 A. I don't recall specifically. 20 Q. When you came back to your 21 practice after the TVT Secur training, 22 did you actually perform TVT Secur 23 operations? 24 A. Yes.</p>
<p style="text-align: right;">Page 31</p> <p>1 tension-free on the urethra but the tape 2 itself could have some and require some 3 tension? 4 MS. GRAFF: Object to form. 5 THE WITNESS: The tape 6 itself has to stay in place. 7 BY MR. ZONIES: 8 Q. And does that require 9 tension? 10 A. I don't know how to answer 11 your question because it rests there. 12 It's like Velcro. So if that's what you 13 define as tension, tension to the 14 retropubic periosteum, if it's a 15 retropubic or to the periurethral fascia 16 obturator, at that point it has to stay 17 in place. So if that for you is tension 18 and your definition of tension, it has to 19 stay in place. 20 Q. When you left the TVT Secur 21 training, did you feel that you were 22 trained well enough to be able to perform 23 the TVT-S surgical procedure? 24 MS. GRAFF: Objection to</p>	<p style="text-align: right;">Page 33</p> <p>1 Q. And that's the two 2 operations you discussed? 3 A. Yes. 4 Q. How did those go? Did you 5 have any complications from those 6 surgeries? 7 A. No complications. 8 Q. Why did you stop using it 9 after those two operations? 10 A. The first case I was not -- 11 it took me much longer to get the fine 12 adjustment that I was looking for and 13 that was significantly for me if my hands 14 length of time compared to a traditional 15 transobturator. 16 The second case I had 17 difficulty releasing the device in place 18 and that basically created an area where 19 there wasn't enough resistance for the 20 TVT Secur to stay in place so I removed 21 the device and put a traditional T-Sling. 22 The patient had no complication. 23 Q. So in other words, in the 24 second one you were describing you</p>

<p style="text-align: right;">Page 34</p> <p>1 attempted to use the TVT Secur and felt 2 that it had failed and so you used a 3 different sling to actually treat the 4 patient? 5 A. I don't know if the device 6 itself failed or my application of the 7 device. The net result would have been a 8 suboptimal result for the patient and I 9 couldn't chance it, so I took it out and 10 put a transobturator sling. 11 Q. Do you have a sense of how 12 many times you have used the Ethicon TVT 13 obturator? 14 A. I can't recall. 15 Q. Do you have a preference for 16 an inside out or an outside in technique 17 for the obturator? 18 A. At this time, outside in is 19 what I have been the most accustomed to. 20 I became comfortable with the outside in 21 when I did Prolift and so outside in just 22 came easier for me. When I teach the 23 residents, you know, I can grip onto the 24 handle with the handle we have. And so</p>	<p style="text-align: right;">Page 36</p> <p>1 more. 2 Q. Can you describe the TVT 3 Obturator inside out approach for me 4 please? How you perform it? 5 A. As best as I can recall, the 6 patient is under anesthesia, she's 7 prepped and draped in the usual fashion. 8 Her bladder is catheterized via Foley. I 9 evaluate the UV junction and figure out 10 where the midurethral area is, take two 11 long Alice clamps, grasp the area just 12 above and just below and cephalocaudal to 13 the midurethral, inject that area with a 14 solution of Marcaine diluted with 15 epinephrine, inject towards the inferior 16 pubic rami on both sides, make a 1.2, 1.4 17 centimeter incision at the level of the 18 midurethra, use a pair of Metzenbaum 19 scissors, open up that periurethral 20 areolar and fascial tissue, what people 21 call fascia, introduce the wing guide at 22 a 45-degree angle, perforate the 23 obturator membrane, take the correct 24 ipsilateral handle depending which way</p>
<p style="text-align: right;">Page 35</p> <p>1 it's easier for me, my preference. My 2 residents learn TVT-O from other 3 physicians, so for me it's my preference. 4 Q. Have you ever taught the 5 TVT-O? 6 A. I'm sure I did. 7 Q. You don't have a 8 recollection though as you sit here? 9 A. There are two hospitals 10 where the TVT-O would have been used and 11 at Apple Hill which is an outpatient 12 facility they don't send residents and 13 they had the TVT-O for many years and 14 Memorial had it and I had the residents 15 there, so I must have. 16 Q. And what was that timeframe? 17 A. Again, that would have been 18 before I went to the T-Sling. 19 Q. Do you think that you've 20 performed fewer than 30 TVT obturators 21 using the Ethicon TVT-O device? 22 A. I can't tell you exactly. 23 Q. It may be fewer than 30? 24 A. It may be fewer; it may be</p>	<p style="text-align: right;">Page 37</p> <p>1 you want to start, right or left, pass it 2 through the wing guide, along the wing 3 guide, and once the tip has reached the 4 obturator membrane, the wing guide goes 5 out, then it's a movement where the hand 6 goes down and rotate and you externalize. 7 I don't make my incisions 8 before I see the tip of my needle because 9 I'll make my incision when the tip of the 10 needle comes out. Then I take a Kocher 11 or Alice clamp, grab the tip, undo the 12 motion so that the actual helical passer 13 can come out, leave the mesh there, 14 perform the same exact procedure on the 15 contralateral side. 16 Once the plastic sheath has 17 been brought out and the mesh is sitting 18 underneath the midurethral but very 19 loose, then I take my Foley catheter out, 20 introduce a 30-degree lens cystoscope for 21 the TOT and TVT-Os. I use a 30-degree 22 lens and explore the urethra, bladder, 23 making sure everything is okay, urethral 24 orifices, leave approximately 200 to 300</p>

<p style="text-align: right;">Page 38</p> <p>1 ML in the patient's bladder depending on 2 what she could hold before with a cough 3 test and stress incontinence. My 4 patients are usually asleep so I do a 5 Crede maneuver for them, make them leak, 6 and then I adjust the tape, and then we 7 cut, pull the plastic sheaths, leave the 8 tape in place. 9 During that time I place a 10 curved Kelly just underneath the 11 midurethra and secure that. Usually my 12 residents are the ones pulling the 13 plastic sheaths. 14 And then I close the 15 incision of course, put the -- pardon me. 16 Once the cysto is done and the cough test 17 is done and put the Foley in, then I put 18 my Kelly, then the plastic sheaths are 19 pulled off, then close incision and then 20 I put a tampon in there in the vagina. 21 Q. So do you have a sense of 22 how soon after the TVT-O came to market 23 that you started to use it? 24 A. I'm not quite sure.</p>	<p style="text-align: right;">Page 40</p> <p>1 or my second case, but I have never had a 2 surgical complication during either -- 3 during any midurethral sling. 4 Q. Do you have a sense of how 5 -- is there a difference in efficacy in 6 your mind between a TVT Retropubic and a 7 TVT Obturator? 8 A. As far as objective, there 9 is about the same, maybe the retropubic 10 TVT would be more efficacious in 11 intrinsic sphincter deficiency patients, 12 but if we look at all of the studies, 13 it's about the same objective and 14 subjective outcome. 15 Q. How about in your personal 16 experience? 17 A. Same. 18 Q. And then how about in 19 complications or adverse effects? Do you 20 find in your experience that there's a 21 difference between your patients who get 22 a TVT or who got a TVT Retropubic and a 23 TVT Obturator? 24 A. So those are two questions.</p>
<p style="text-align: right;">Page 39</p> <p>1 Q. Do you have a preference for 2 the retropubic or obturator approach? 3 A. I have no personal 4 preference. It depends on the patient. 5 It depends on her indications, 6 contraindications, what her pathology is, 7 does she have intrinsic sphincter 8 deficiency, you know, what else is going 9 on and what has she had done previously, 10 if I'm seeing her for a previously 11 failed, you know, incontinence procedure. 12 So everything will be tailored to the 13 patient. 14 Q. If you have a woman who has 15 intrinsic sphincter deficiency, do you 16 lean towards retropubic or obturator? 17 A. I would lean to retropubic, 18 yes. 19 Q. When you began using the TVT 20 Retropubic, did you have any 21 complications with any of your patients 22 during the surgical procedure? 23 A. Yes. I buttonholed the 24 vaginal mucosa, I think it was my first</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Uh-huh. 2 A. If we look at overall 3 complication rates, no difference. Are 4 there subtleties? Yes, because the 5 retropubic TVT passes in Retzius, there's 6 complications specifically associated 7 with Retzius space and intraabdominal 8 complication. There are vascular 9 complications in both but the vessels can 10 be different just because we're not 11 entering through the same space. The 12 area of pain and discomfort will be 13 different just because suprapubic versus 14 between the inner thighs, so those things 15 specifically will be different, but 16 overall success/failure, about the same. 17 Q. And again, is that based on 18 your experience or based on your 19 literature review or both? 20 A. Both. 21 Q. When you were using the TVT 22 Obturator, were you using mechanically 23 cut mesh or laser cut mesh? 24 A. At the time it is</p>

<p style="text-align: right;">Page 42</p> <p>1 mechanically cut. I think it is 2 mechanically cut. 3 Q. Did you ever use a TVT 4 Retropubic or a TVT Obturator that was 5 made with laser cut mesh? 6 A. I don't recall. 7 Q. Have you ever had to remove 8 a midurethral sling that you had 9 implanted? 10 A. Yes. 11 Q. Tell me about that. How 12 many times? 13 A. And let me be more -- or ask 14 a more precise -- are we talking about 15 the entire sling? 16 Q. Okay. 17 A. Or are we just talking about 18 adjustment cut? I think that's a fair 19 question. 20 Q. Let's break it down. Have 21 you ever had to remove an entire TVT 22 Retropubic or a TVT Obturator sling? 23 A. So for the TVT Retropubic 24 that I have personally put in, yes.</p>	<p style="text-align: right;">Page 44</p> <p>1 A. Not the entire sling, no. 2 Q. How about a TVT Obturator? 3 Have you ever removed an entire TVT 4 Obturator sling? 5 A. The entire? Going into the 6 adductus muscles and obturator, no, I 7 have not. 8 Q. Would that be difficult to 9 do? Is that why you say it that way? 10 That going in through the adductor 11 muscles would be a much more invasive and 12 difficult procedure to remove the mesh? 13 A. No. I'm just saying it to 14 make sure that I'm as precise as you are. 15 When you say entire removal, it means 16 entire removal. 17 Q. And you've never done that? 18 A. I've never had to do that. 19 Q. Do you know if any of your 20 patients, any of the patients that you 21 implanted have ever had to have their 22 entire TVT Retropubic or TVT Obturator 23 removed by another physician? 24 A. Not to my knowledge.</p>
<p style="text-align: right;">Page 43</p> <p>1 Once. 2 Q. And what led to that? 3 A. The patient was convinced 4 her fatty liver was caused by the TVT 5 sling even though she had absolutely no 6 problems. She claimed other ailments and 7 just absolutely wanted it out. I sent 8 her to a gastroenterologist, a 9 rheumatologist, her internal medicine 10 person, this patient was also on some 11 antidepressant and other medication, 12 morbidly obese, and at one point had to 13 acquiesce and removed it. 14 Q. And that was a TVT 15 Retropubic? 16 A. That was a TVT Retropubic. 17 Q. And about when did that 18 occur? 19 A. Early on. Basically between 20 2002 and 2005. Something like that. 21 Q. Other than that one time 22 when you removed an entire TVT 23 Retropubic, have you removed any other 24 TVT Retropubics? The entire sling?</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Have you ever had to remove 2 part of a TVT Obturator sling? 3 A. I can't recall if it was -- 4 TVT Obturator? Yes. 5 Q. Tell me about that. 6 A. That I put in? 7 Q. Yes. 8 A. Oh! I don't think it was a 9 TVT Obturator. It was a TOT. An out to 10 in. 11 Q. Is the T-Sling an out to in 12 sling? 13 A. It's an out to in. 14 Q. And what about a TVT 15 Retropubic? Have you ever had to -- 16 A. Remove part of it? Yes. 17 That I put in, no. 18 MS. GRAFF: Doctor, please 19 let him finish his question before 20 you answer. 21 THE WITNESS: Sorry. 22 BY MR. ZONIES: 23 Q. You haven't had to remove 24 any TVT -- it sounds like your testimony</p>

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1 is that you haven't had to remove any TVT
 2 Retropubics or TVT Obturator even in part
 3 that you put in in the first instance;
 4 correct?
 5 A. I'm trying to think here.
 6 Not that I can recall.
 7 Q. Have you ever treated any of
 8 the patients for whom you've put in a TVT
 9 or TVT-O sling, have you ever treated
 10 them for an erosion?
 11 A. Not a TVT-O. An out to in,
 12 yes, vaginal, but not --
 13 Q. Vaginal erosion for a --
 14 A. Out to in, but not
 15 specifically the TVT-O.
 16 Q. Okay. You treat women who
 17 have had complications from mesh that was
 18 implanted by other physicians; correct?
 19 A. I do.
 20 Q. Is that a significant part
 21 of your practice?
 22 A. Not more than 51 percent if
 23 that's what you calculate, no.
 24 Q. What percentage of your

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1 practice is treating mesh complications?
 2 A. Less than ten percent.
 3 Q. Less than ten percent?
 4 A. Less than ten percent.
 5 Q. Have you ever treated a
 6 patient for an erosion who had a TVT
 7 Obturator device?
 8 A. I may have. I can't recall.
 9 Q. Have you ever removed a TVT
 10 Obturator device?
 11 A. Partially?
 12 Q. Yes.
 13 A. In somebody that I didn't
 14 put in, yes.
 15 Q. And how often have you done
 16 that?
 17 A. Ten times maybe.
 18 Q. How do you know it was a TVT
 19 Obturator?
 20 A. Because I get the operative
 21 reports.
 22 Q. Do you do that for all of
 23 the patients for whom you're treating for
 24 a mesh complication?

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1 A. All of the patients that I
 2 didn't put it in I get the operative
 3 report because I would have the operative
 4 report if they were mine.
 5 Q. And why is that important
 6 for you to get the operative report?
 7 A. I want to know exactly what
 8 mesh I'm dealing with, where they said
 9 they implanted it, what other risks,
 10 complications happened during the case.
 11 It just helps me see ahead of time if
 12 there are any additional risks or any
 13 other additional factors that I would be
 14 dealing with before I bring a patient to
 15 the OR.
 16 Q. And in those patients where
 17 you've excised some of a TVT Obturator
 18 device, what were the indications for
 19 removing the mesh?
 20 A. Pain, erosion. Erosion into
 21 the vagina and pelvic pain.
 22 Q. So in your practice for at
 23 least these ten times you felt it was an
 24 appropriate scientific and medical

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1 procedure to remove a portion of a TVT-O
 2 sling when the complaints were of pelvic
 3 pain; correct?
 4 A. You say scientific.
 5 Q. And I meant medical.
 6 A. After thorough evaluation,
 7 after conservative measures, after pelvic
 8 floor therapy, if I feel that there was a
 9 significant amount of pain that was
 10 located at the insertion of the mesh
 11 material into the pelvic floor and that
 12 set off a trigger point and conservative
 13 measures didn't work, then at that point
 14 it's a discussion with the patient
 15 knowing that the risk of recurrence of
 16 incontinence, you know, is 25 to 30
 17 percent, sometimes even more.
 18 Q. And you've done that for
 19 patients who have presented with pelvic
 20 pain; correct?
 21 A. What do you mean "done
 22 that"?
 23 Q. Sorry. You have removed a
 24 TVT Obturator sling or part of a TVT

<p style="text-align: right;">Page 50</p> <p>1 Obturator sling for patients who have 2 presented to you with pelvic pain after 3 doing a thorough analysis that it was a 4 medically necessary and correct 5 procedure? 6 A. Correct. 7 Q. You've also done that 8 separately for patients who have had a 9 TVT Obturator, you have removed some of 10 the TVT Obturator mesh when those 11 patients have presented to you with an 12 erosion because you felt it was a 13 medically necessary and reasonable 14 surgery; correct? 15 A. Correct. 16 Q. In those cases where you've 17 done that, was there relief from the pain 18 in those cases? 19 A. Most, yes. 20 Q. And you discussed that prior 21 to taking the surgical step of removing 22 the mesh you would also attempt other 23 noninvasive methods to help the patients 24 with the pain; is that right?</p>	<p style="text-align: right;">Page 52</p> <p>1 Q. I understand, but in these 2 ten patients for example where ultimately 3 you surgically had to remove -- 4 A. Yes. 5 Q. -- part of the mesh, in 6 those patients when you finally got to 7 that point of needing to do a surgical 8 intervention, prior to that surgical 9 intervention you would have tried more 10 conservative measures to manage their 11 pain that obviously did not work. Is 12 that fair? 13 A. That is correct, unless 14 they've already had the conservative 15 measures done elsewhere. 16 Q. Understood. And so it 17 sounds to me like that's some number of 18 months of trying to manage the pain prior 19 to the surgical procedure. Is that fair? 20 MS. GRAFF: Object to form. 21 THE WITNESS: I wouldn't say 22 months. It just depends on when 23 they come to my doorstep and what 24 I think the appropriate course of</p>
<p style="text-align: right;">Page 51</p> <p>1 A. That is correct. I just 2 want to make sure that we're separating 3 here the need to correct an erosion of a 4 mesh from a patient presenting with 5 pelvic floor pain or pelvic pain that 6 also happens to have a transobturator 7 sling mesh. Those are two separate 8 pathology, etiology, management, and two 9 different types of intervention. 10 Q. Understood. So if you have 11 a patient presenting with pelvic pain who 12 has a TVT Obturator, your first steps 13 would be to try to conservatively manage 14 that pain? 15 A. The first step would be to 16 evaluate where the pain is coming from. 17 Plenty of women have pelvic pain and 18 pelvic floor dysfunction and a lot of 19 conditions that produce pain and have 20 never had any mesh or sling procedures. 21 So one doesn't preclude the other, and 22 it's not because somebody comes in and 23 had a previous sling that her pain is 24 consequently due to the sling.</p>	<p style="text-align: right;">Page 53</p> <p>1 action is. 2 BY MR. ZONIES: 3 Q. Have you had the experience 4 of a case where you've removed part of 5 the mesh and it did not resolve the pain? 6 A. Yes. 7 Q. In those cases, what is your 8 next step? Do you take a step to remove 9 more of the mesh? 10 A. It depends. Last case that 11 came to mind -- that comes to mind is a 12 patient who had severe pelvic floor 13 dysfunction and we're not quite sure if 14 it was caused by the mesh or not. There 15 was not a hundred percent relief. And I 16 have somebody that I refer to that can do 17 neurolysis and specific pudendal nerve 18 releases, so she's at that point. 19 Q. Continued attempts to 20 resolve the pain despite having the mesh 21 partially excised? 22 A. Correct. And the entire 23 left side was removed, and she had no 24 stress incontinence after the removal. I</p>

<p style="text-align: right;">Page 54</p> <p>1 did not put the mesh in. And so she's a 2 complex case of pelvic pain and we're not 3 quite sure what hit first, so ... 4 And may I add one more thing 5 in that particular patient? Her left arm 6 of whatever the mesh that was put in was 7 into the levator ani muscle group. It 8 was asymmetrically positioned in her. 9 Q. And was that a TVT 10 Obturator? 11 A. TVT Obturator. 12 Q. This risk of pelvic pain 13 associated with a TVT Obturator, is that 14 something that you inform your patients 15 about prior to -- or informed your 16 patients about prior to using a TVT 17 Obturator device on them? 18 A. The risk of pelvic pain 19 is -- I inform my patients of the risk of 20 pelvic pain while doing any surgery to 21 the pelvic floor. So whether it's a TVT, 22 TOT, TVT-O, hysterectomy, pelvic 23 reconstruction, you touch the pelvic 24 floor, there can be pain.</p>	<p style="text-align: right;">Page 56</p> <p>1 wouldn't have had that type of 2 discussion. 3 But when we go through 4 options to manage urinary stress 5 incontinence and we've gone from 6 the nonsurgical to the surgical, 7 once we get to the surgical, 8 whatever procedure there is 9 described in the literature can 10 and is associated with pelvic pain 11 in some patients to a certain 12 degree. 13 So no matter what, 14 anesthesia is associated with the 15 risk of death, so when I do and 16 talk about, listen, we're at a 17 point where you may need surgery, 18 the considerations are and include 19 bladder perforation, urethral 20 damage, pain, chronic pain, 21 dyspareunia, heart attack, stroke, 22 laparotomy. So all of these are 23 discussed with the patient ahead 24 of time.</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. But specifically with a 2 TVT-O or a midurethral sling like the 3 TVT-O, do you say to your patients, look, 4 I've had an experience where after 5 implanting a TVT-O a patient -- or strike 6 that. 7 Specifically with regard to 8 TVT-O, do you have discussions with your 9 patients saying I've had experiences 10 where a patient has had a TVT-O inserted 11 and they've experienced severe pelvic 12 pain and I remove a portion of that mesh 13 and it can relieve the pain? 14 MS. GRAFF: Object to form. 15 BY MR. ZONIES: 16 Q. Have you ever had that 17 discussion with a patient? 18 MS. GRAFF: Objection. 19 THE WITNESS: Well, I 20 wouldn't have had that specific 21 discussion because I have had not 22 experience with TVT-O that caused 23 pelvic pain that I needed to 24 remove part of the mesh. So I</p>	<p style="text-align: right;">Page 57</p> <p>1 BY MR. ZONIES: 2 Q. And then when you have a 3 patient present like one of these ten 4 TVT-O patients you discussed with a 5 complication of pelvic pain, at that 6 point you have an informed consent 7 discussion with that patient as well; 8 correct? 9 A. Absolutely. 10 Q. And during that informed 11 content conversation with a patient who's 12 presenting with pelvic pain from a TVT-O, 13 you inform that patient that you've had 14 success removing some of the TVT-O mesh 15 to alleviate the pain. Is that right? 16 MS. GRAFF: Object to form. 17 THE WITNESS: Yes, that is 18 correct. 19 BY MR. ZONIES: 20 Q. And when you're having that 21 informed consent discussion with that 22 patient, you say to do this procedure of 23 removing the mesh there are risks? 24 A. That is correct.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. And you go through the list 2 of risks very similar to the ones you 3 just named for me saying because this is 4 a surgical procedure there's a risk when 5 I remove this mesh of bleeding. You tell 6 the patient that; right? 7 A. Yes. 8 Q. There's a risk of de novo 9 pelvic pain associated with removing a 10 mesh; is that true? 11 A. Right, but if they're 12 already coming to me for pain and I'm 13 going to remove the mesh, the word de 14 novo doesn't apply. 15 Q. I meant to say worsening 16 pelvic pain. 17 A. Yes. And may I add one 18 thing? 19 Q. Sure. 20 A. Mesh erosion, I forgot to 21 mention it and the risk of me placing a 22 mesh sling, that would have gone into 23 your previous question. 24 Q. That's one of the -- what</p>	<p style="text-align: right;">Page 60</p> <p>1 consenting of a patient exist again for 2 this surgical operation on the pelvic 3 floor; correct? 4 MS. GRAFF: Object to form. 5 THE WITNESS: It depends on 6 the patient, and I'll just do a 7 caveat. The risk of erosion 8 depends on how much is left and 9 where it's left. So, if we go and 10 dissect to the obturator internus 11 and we remove that mesh, well, 12 whatever is left on that pelvic 13 side wall cannot erode therefore 14 in the vagina. What is left of 15 the mesh depending on where it is 16 can if there's still mesh in that 17 general area. 18 BY MR. ZONIES: 19 Q. In patients when you are 20 removing a portion of a TVT-O sling, do 21 you use general anesthesia usually? 22 A. Yes. 23 Q. So those patients have the 24 risks, all of the risks associated with</p>
<p style="text-align: right;">Page 59</p> <p>1 you're trying to say is is that in 2 addition to what I'll call creative 3 horribles of outcomes, you would also 4 have erosion in there as one of your 5 consenting risks? 6 A. I would have mesh erosion as 7 one of my original consent risks. 8 Q. And you would also have 9 erosion as one of your consent risks for 10 a patient for whom you're about to remove 11 some of the mesh, correct, because 12 there's a chance of erosion associated 13 with removing a portion of the mesh? 14 A. It would be associated with 15 the portion that has not been removed, 16 yes. 17 Q. And you would also -- so if 18 a patient has a TVT-O implanted and 19 presents to you with pelvic pain, in your 20 discussion with that patient about the 21 risks of a now second surgery that would 22 be to remove a portion of the mesh, you 23 would go through the same risks because 24 all those risks as in your original</p>	<p style="text-align: right;">Page 61</p> <p>1 general anesthesia when you're doing a 2 removal of the mesh; correct? 3 A. Let me caveat that. Not all 4 of them are under general anesthesia. 5 The ones that are on general anesthesia 6 are the ones that I remove for pelvic 7 pain. 8 Q. Some of them may be however? 9 A. Some? 10 Q. Yeah. 11 A. If I have a simple vaginal 12 erosion, I may do that in the office 13 local anesthesia, you know; but if I feel 14 that there is a portion of the mesh that 15 is placed through the levator ani muscle, 16 then that patient is going to be under 17 general anesthesia for her patient 18 comfort. 19 Q. So there are some of the 20 patients whom you've treated for mesh 21 complications such as pelvic pain where 22 you're removing a portion of a TVT 23 Obturator sling for whom you've had to 24 use general anesthesia; correct?</p>

<p style="text-align: right;">Page 62</p> <p>1 A. That would be correct.</p> <p>2 Q. And those patients who are</p> <p>3 having this re-operation to remove a</p> <p>4 portion of the mesh have all of the risks</p> <p>5 associated with going under general</p> <p>6 anesthesia including, for example, death;</p> <p>7 correct?</p> <p>8 A. Yes, although pretty darn</p> <p>9 rare. Good anesthesia nowadays, but yes.</p> <p>10 Q. And those patients would</p> <p>11 have the risk of bleeding from the</p> <p>12 surgical procedure to remove the mesh;</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. They would also have the</p> <p>16 risk of dyspareunia associated with any</p> <p>17 pelvic floor surgery; correct?</p> <p>18 A. Right, but if I'm removing</p> <p>19 it for pain, most of these women have</p> <p>20 dyspareunia if they're sexually active.</p> <p>21 Q. That's a good point. To you</p> <p>22 it sounds like pelvic pain includes</p> <p>23 within it dyspareunia?</p> <p>24 A. No. They can be mutually</p>	<p style="text-align: right;">Page 64</p> <p>1 device company who was making such a mesh</p> <p>2 to inform physicians and patients that</p> <p>3 removal of the mesh may be necessary to</p> <p>4 relieve pelvic pain?</p> <p>5 MS. GRAFF: Object to form.</p> <p>6 THE WITNESS: Specifically</p> <p>7 talking about TVT-O? Is that what</p> <p>8 you're asking?</p> <p>9 BY MR. ZONIES:</p> <p>10 Q. Yes. Do you think it would</p> <p>11 be appropriate and necessary for a</p> <p>12 medical device manufacturer to include in</p> <p>13 the instructions for use and the patient</p> <p>14 brochure the fact that there's a risk</p> <p>15 that the TVT-O mesh may need to be</p> <p>16 removed in a second surgical procedure?</p> <p>17 A. I think that -- let me</p> <p>18 rephrase this. It's my opinion that</p> <p>19 urinary stress incontinence surgery can</p> <p>20 always carry a risk of needing to have</p> <p>21 sutures removed, mesh removed whether</p> <p>22 it's a pubovaginal sling or a midurethral</p> <p>23 sling for many years. So every surgeon</p> <p>24 that puts in a foreign body has to know</p>
<p style="text-align: right;">Page 63</p> <p>1 inclusive or not.</p> <p>2 Q. So my question is have you</p> <p>3 ever removed a TVT-O mesh where the</p> <p>4 indication was dyspareunia?</p> <p>5 A. Along with pelvic pain, yes.</p> <p>6 MR. ZONIES: Let's take a</p> <p>7 break.</p> <p>8 (Whereupon, a brief recess</p> <p>9 was held from 2:42 to 2:51 p.m.)</p> <p>10 BY MR. ZONIES:</p> <p>11 Q. Doctor, before we broke we</p> <p>12 were discussing your medical treatment of</p> <p>13 some women who had had complications</p> <p>14 associated with their TVT-O sling. Do</p> <p>15 you recall those conversations?</p> <p>16 A. Yes.</p> <p>17 Q. And your treatment of those</p> <p>18 women, for some of them you had to</p> <p>19 perform a second surgical procedure to</p> <p>20 remove part of the TVT-O mesh; is that</p> <p>21 right?</p> <p>22 A. That would be correct.</p> <p>23 Q. Do you think it would be</p> <p>24 appropriate and necessary for a medical</p>	<p style="text-align: right;">Page 65</p> <p>1 that there's a risk that part of it may</p> <p>2 need to be removed for any reason.</p> <p>3 So is it necessary to inform</p> <p>4 each doctor specifically that the TVT-O</p> <p>5 needs to have this information? I think</p> <p>6 with our training, with our experience,</p> <p>7 with any of the literature it would not</p> <p>8 be necessary or it should not be</p> <p>9 necessary.</p> <p>10 Q. You don't know what's in</p> <p>11 every other physician's head; correct?</p> <p>12 A. Correct. I am not a mind</p> <p>13 reader.</p> <p>14 Q. Right. And so for a</p> <p>15 physician who is just starting to use</p> <p>16 midurethral slings such as the TVT-O,</p> <p>17 don't you think it would be appropriate</p> <p>18 to include in the instructions for use,</p> <p>19 hey, you should know that in some</p> <p>20 instances it's been reported that women</p> <p>21 who have had a TVT-O implanted have</p> <p>22 experienced pelvic pain and dyspareunia</p> <p>23 and despite conservative measures to</p> <p>24 treat that pelvic pain and dyspareunia it</p>

<p style="text-align: right;">Page 66</p> <p>1 did not resolve which necessitated 2 removal of some or all of the sling? 3 Wouldn't that be appropriate? 4 A. What is more appropriate I 5 would think is that if a physician is 6 just starting now to do midurethral sling 7 with the amount of body of literature 8 that's out there that that person would, 9 one, read what's out there or part of it, 10 make themselves aware of at least the 11 latest Cochrane Reviews on midurethral 12 sling, get appropriate training and that 13 would include risks and complications. 14 Q. And you're speaking about a 15 physician who would start today, but what 16 about when you started to do slings? 17 When you first started to do slings, did 18 you know that in 2002, 2003, 2005, did 19 you have an appreciation that there was a 20 risk of pelvic pain and dyspareunia 21 associated with the use of a TVT device 22 and that the only way to get relief if 23 possible would be removal of the device? 24 MS. GRAFF: Object to form.</p>	<p style="text-align: right;">Page 68</p> <p>1 didn't expect that there could be no 2 association with pain by placing a 3 polypropylene mesh underneath the 4 midurethra. We would have risks just 5 like a sacrocolpopexy has risks of pain. 6 Q. And is that something that 7 in that timeframe in the early 2000s 8 through mid 2000s, is that something that 9 you believe patients should also have 10 been informed of? 11 A. I think it's part of the 12 informed consent and to have to redo 13 surgery is part of the informed consent 14 that things may not last, so I believe 15 that there's enough out there that it's 16 not an absolute necessity to have it 17 spelled out on an IFU. 18 Q. What about in a brochure 19 that's advertising the product? 20 Shouldn't you put the risk of resurgery 21 in that brochure? 22 MS. GRAFF: Objection. 23 THE WITNESS: It depends on 24 what the brochure is intended to</p>
<p style="text-align: right;">Page 67</p> <p>1 THE WITNESS: Can you repeat 2 that? I'm sorry. 3 BY MR. ZONIES: 4 Q. Sure. When you first 5 started to use TVT slings and the TVT-O 6 in 2002 through say 2005 timeframe, did 7 you understand that there was a risk of 8 severe pelvic pain and dyspareunia with 9 the use of a TVT-O and that conservative 10 measures of treating that pain might not 11 work such that you would recommend and 12 perform a surgical procedure to remove 13 the mesh in a patient? 14 MS. GRAFF: Object to form. 15 BY MR. ZONIES: 16 Q. Did you know that? 17 MS. GRAFF: Same objection. 18 THE WITNESS: I think I did. 19 BY MR. ZONIES: 20 Q. And from where did you learn 21 that? 22 A. Experience, previous 23 knowledge of putting burst sutures that, 24 you know, would have to be removed. I</p>	<p style="text-align: right;">Page 69</p> <p>1 do. I think if you put every 2 possible risk that could occur on 3 a brochure, since those risks are 4 not more likelier than not to 5 occur, then it defies the purpose 6 of the brochure. I think the 7 brochure in general for patients 8 is intended for general use, that 9 the broad risks are explained and 10 that a secondary surgery could be 11 necessary. 12 BY MR. ZONIES: 13 Q. And that's certainly 14 something that a patient should be 15 informed of, that a secondary surgery 16 could be necessary; correct? 17 MS. GRAFF: Objection. 18 Mischaracterizes. 19 THE WITNESS: For any reason 20 for any surgeon. 21 BY MR. ZONIES: 22 Q. Including for a TVT-O? 23 A. Including for TVT-O. 24 Q. And a patient should be</p>

<p style="text-align: right;">Page 70</p> <p>1 informed and consented that implantation 2 of a TVT-O could lead to severe pelvic 3 pain that is not resolvable absent 4 another surgery removing the mesh; 5 correct?</p> <p>6 MS. GRAFF: Are you talking 7 about the brochure or are you 8 talking about the consent that she 9 has with her patient?</p> <p>10 MR. ZONIES: Thank you.</p> <p>11 BY MR. ZONIES:</p> <p>12 Q. Either through the brochure 13 or through the physician's discussion 14 with the patient, a patient should be 15 informed when getting a TVT-O device that 16 there is a risk that the patient will 17 experience severe pelvic pain from the 18 TVT-O device that can only be relieved by 19 removing the device; correct?</p> <p>20 MS. GRAFF: Objection to the 21 form, to the word "should". 22 You can answer if you can.</p> <p>23 THE WITNESS: It is my 24 experience that chronic pelvic</p>	<p style="text-align: right;">Page 72</p> <p>1 MS. GRAFF: Object to form.</p> <p>2 BY MR. ZONIES:</p> <p>3 Q. You inform your patients of 4 that; correct?</p> <p>5 MS. GRAFF: Same objection.</p> <p>6 THE WITNESS: I tell them 7 that there is a risk that they can 8 have chronic pain.</p> <p>9 BY MR. ZONIES:</p> <p>10 Q. Do you tell them that 11 there's a risk that they can have 12 permanent pain?</p> <p>13 A. Yes.</p> <p>14 Q. Do you tell them that 15 there's a risk that they can have pain 16 that will lead to a second surgery to 17 remove the TVT-O device and even that 18 surgery may not correct the pain?</p> <p>19 MS. GRAFF: Objection.</p> <p>20 THE WITNESS: Any patient 21 after any surgery, mesh, non-mesh, 22 synthetic sling or not, 23 pubovaginal sling, Burch procedure 24 has a risk of permanent pain, has</p>
<p style="text-align: right;">Page 71</p> <p>1 pain is a known risk associated 2 with any pelvic and/or urological 3 procedure and that should be part 4 of the informed consent.</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. Right. A patient should be 7 informed of that; correct?</p> <p>8 A. Should be informed of the 9 risk of chronic pelvic pain.</p> <p>10 Q. Should also be informed that 11 there is a risk with the insertion of a 12 TVT Obturator device of chronic permanent 13 dyspareunia; correct?</p> <p>14 MS. GRAFF: Object to form.</p> <p>15 THE WITNESS: Part of the 16 chronic pain syndrome, I inform my 17 patients about chronic pelvic pain 18 on every procedure. Scarring even 19 normal can lead to pain.</p> <p>20 BY MR. ZONIES:</p> <p>21 Q. And in particular you inform 22 them that there is a risk of permanent 23 debilitating dyspareunia with the use of 24 a TVT-O device?</p>	<p style="text-align: right;">Page 73</p> <p>1 a risk of needing a secondary 2 procedure for any reason that is 3 medically necessary that may or 4 may not correct the problem.</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. And that is something that 7 you believe you have an obligation to 8 inform your patients of prior to 9 implanting a TVT-O device; correct?</p> <p>10 A. Prior to implanting any 11 device I would inform them that they have 12 a risk of chronic pelvic pain and 13 dyspareunia.</p> <p>14 Q. And resurgery?</p> <p>15 A. And they may need a 16 secondary surgery, yes, for a medically 17 necessary reason. Yes.</p> <p>18 Q. And for example, in those 19 ten women where you removed part of the 20 TVT Obturator, it was a medically 21 necessary operation?</p> <p>22 A. Correct.</p> <p>23 Q. Doctor, I'm going to hand 24 you what's going to be marked Exhibit 1</p>

<p style="text-align: right;">Page 74</p> <p>1 to this deposition?</p> <p>2 (Whereupon, the court</p> <p>3 reporter marked Exhibit 1 for</p> <p>4 identification as of this date.)</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. And Doctor, this is the TVT</p> <p>7 Obturator Instructions for Use. Do you</p> <p>8 recognize it as such?</p> <p>9 A. Yes.</p> <p>10 Q. And I'll have you turn</p> <p>11 please to the Page 7 entitled Adverse</p> <p>12 Reactions. Do you see that section?</p> <p>13 A. Yes.</p> <p>14 Q. So Doctor, under Adverse</p> <p>15 Reactions, do you believe that it was</p> <p>16 appropriate and necessary to include in</p> <p>17 the IFU the adverse reaction of punctures</p> <p>18 or lacerations of vessels, nerves,</p> <p>19 structures or organs including the</p> <p>20 bladder, urethra or bowel may occur and</p> <p>21 may require surgical repair?</p> <p>22 MS. GRAFF: Objection. Was</p> <p>23 it necessary? Was that your</p> <p>24 question.</p>	<p style="text-align: right;">Page 76</p> <p>1 handled a scalpel would know that</p> <p>2 there is a transitory local</p> <p>3 irritation at the site of the</p> <p>4 wound. Is it necessary? I don't</p> <p>5 know what the FDA required for</p> <p>6 this IFU.</p> <p>7 BY MR. ZONIES:</p> <p>8 Q. But again you don't know</p> <p>9 what is in surgeons' heads about the</p> <p>10 risks that they do or don't know about;</p> <p>11 correct?</p> <p>12 A. I, again, am not going to</p> <p>13 pretend to know what's in every surgeon,</p> <p>14 but I would expect that surgeons would</p> <p>15 know that if they make an incision that</p> <p>16 there will be inflammation in order for</p> <p>17 this incision to heal. It's part of the</p> <p>18 normal healing process.</p> <p>19 Q. The third bullet down for</p> <p>20 adverse reactions is "as with any</p> <p>21 implant, a foreign body response may</p> <p>22 occur".</p> <p>23 You agree that with the</p> <p>24 implantation of a TVT-O device in every</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. ZONIES: Yes.</p> <p>2 BY MR. ZONIES:</p> <p>3 Q. Was it reasonable and</p> <p>4 necessary to include that risk?</p> <p>5 A. I think it's very</p> <p>6 reasonable. Was it necessary? I don't</p> <p>7 know what is necessary in the formulation</p> <p>8 of an IFU or what is required, but this</p> <p>9 is certainly very reasonable.</p> <p>10 Q. And same question with</p> <p>11 respect to the second adverse reaction in</p> <p>12 the IFU, "transitory local irritation at</p> <p>13 the wound site may occur".</p> <p>14 That's reasonable and</p> <p>15 necessary to include in the IFU; correct?</p> <p>16 MS. GRAFF: Objection.</p> <p>17 THE WITNESS: I think it is,</p> <p>18 in my opinion, it is very</p> <p>19 reasonable; and again, is it</p> <p>20 necessary for a surgeon to know</p> <p>21 that once you make an incision and</p> <p>22 there's a wound that there's a</p> <p>23 transitory local irritation? I</p> <p>24 think most surgeons who have</p>	<p style="text-align: right;">Page 77</p> <p>1 instance a foreign body response occurs;</p> <p>2 correct?</p> <p>3 A. With the implantation of any</p> <p>4 foreign body, a foreign body response</p> <p>5 will occur.</p> <p>6 Q. Will occur; correct?</p> <p>7 A. Will.</p> <p>8 Q. Not may as the IFU says;</p> <p>9 correct?</p> <p>10 A. Correct.</p> <p>11 Q. And it goes on to say this</p> <p>12 response could result in extrusion,</p> <p>13 erosion, exposure, fistula formation</p> <p>14 and/or inflammation. You agree with that</p> <p>15 as well; correct?</p> <p>16 A. I agree that a foreign body</p> <p>17 response can result in all of these, yes.</p> <p>18 Q. And the next bullet point</p> <p>19 down says mesh extrusion, exposure or</p> <p>20 erosion into the vagina or other</p> <p>21 structures or organs.</p> <p>22 You agree that that is a</p> <p>23 potential adverse reaction associated</p> <p>24 with the use of a TVT-O device; correct?</p>

<p style="text-align: right;">Page 78</p> <p>1 A. I believe it is associated 2 with the TVT-O or any other mesh, yes. 3 Q. And so it's appropriate for 4 that to be in the IFU; correct? 5 A. I think it was appropriate 6 to be in the IFU. 7 Q. Is that necessary to be in 8 the IFU? 9 MS. GRAFF: Object to form. 10 THE WITNESS: I don't know 11 what the FDA again requires as 12 necessary, but it was appropriate 13 to be placed here. 14 BY MR. ZONIES: 15 Q. If Ethicon knew of that risk 16 and decided not to put that in the IFU, 17 would that be inappropriate? 18 MS. GRAFF: Object to form. 19 THE WITNESS: Again, I don't 20 know what is necessary by FDA 21 standards in the formulation of an 22 IFU, but surgeons who use prolene 23 or polypropylene mesh would know 24 that there's a risk of mesh</p>	<p style="text-align: right;">Page 80</p> <p>1 Q. You've never had a TVT 2 Retropubic sling that became severely 3 infected? 4 A. No. 5 Q. You've never referred a 6 patient of yours with a TVT sling to an 7 infectious disease doctor to deal with 8 the infection? 9 A. No, not for that. I 10 referred the previously mentioned patient 11 to an infectious disease specialist to 12 confirm that there was no infection for 13 the patient's satisfaction and no 14 infection was found at the removal of her 15 entire TVT site. 16 Q. Her TVT was eventually 17 removed? 18 A. Yes, as previously 19 discussed. 20 Q. And who removed that TVT? 21 A. I did. It was sent to 22 pathology. 23 Q. Do you send all of the 24 meshes that you have removed to</p>
<p style="text-align: right;">Page 79</p> <p>1 extrusion, exposure, erosion into 2 the vagina or other structures or 3 organs; even with sacrocolpopexies 4 this will occur. 5 BY MR. ZONIES: 6 Q. Did you administer 7 prophylactic antibiotics when you 8 implanted TVT-O? 9 A. Yes. 10 Q. In every case? 11 A. Every case. 12 Q. Do you believe that's the 13 medically correct way to handle a TVT-O 14 implantation? 15 A. In my experience, I 16 administer antibiotic prophylaxis for any 17 vaginal surgery that requires an incision 18 of the vaginal mucosa. 19 Q. Have you ever experienced a 20 midurethral sling becoming infected -- 21 A. No. 22 Q. -- and necessitating removal 23 of the sling? 24 A. No.</p>	<p style="text-align: right;">Page 81</p> <p>1 pathology? 2 A. I do. 3 Q. And do you review those 4 pathology reports? 5 A. I do. 6 Q. Have you ever seen a 7 pathology report discuss degradation of 8 mesh? 9 A. No. 10 MR. ZONIES: Could we go off 11 the record a second? 12 (Whereupon, a discussion was 13 held off the record from 3:14 p.m. 14 to 3:16 p.m.) 15 BY MR. ZONIES: 16 Q. Do you have that IFU still 17 in front of you, Doctor? 18 A. Yes. 19 Q. Doctor, we were reviewing 20 Exhibit 1, the IFU for the TVT-O and a 21 few bullets down from where we just were 22 there's a line that says an adverse 23 reaction is acute and/or chronic pain. 24 Do you see that?</p>

<p style="text-align: right;">Page 82</p> <p>1 A. I do see that.</p> <p>2 Q. And you would agree that</p> <p>3 that's a risk with a TVT-O; correct?</p> <p>4 A. As with any surgery, yes.</p> <p>5 Q. But it is a risk with a</p> <p>6 TVT-O; correct?</p> <p>7 A. It is.</p> <p>8 Q. So it's appropriate for that</p> <p>9 to be in the IFU in your opinion;</p> <p>10 correct?</p> <p>11 A. It is appropriate.</p> <p>12 Q. And then voiding dysfunction</p> <p>13 is the next one. That's also appropriate</p> <p>14 to be in the IFU; correct?</p> <p>15 A. It is appropriate to be in</p> <p>16 the IFU.</p> <p>17 Q. The next one, pain with</p> <p>18 intercourse which in some patients may</p> <p>19 not resolve, that's appropriate to be in</p> <p>20 the IFU and to inform physicians of;</p> <p>21 correct?</p> <p>22 A. It is appropriate to be in</p> <p>23 the IFU and it's there.</p> <p>24 Q. Neuromuscular problems</p>	<p style="text-align: right;">Page 84</p> <p>1 hemorrhage or hematoma, that is a risk</p> <p>2 associated with the TVT-O device;</p> <p>3 correct?</p> <p>4 A. As with any other surgery.</p> <p>5 Q. So bleeding including</p> <p>6 hemorrhage or hematoma is a risk of the</p> <p>7 TVT-O device; correct?</p> <p>8 A. It is.</p> <p>9 Q. And so it's appropriate that</p> <p>10 that be in the IFU; correct?</p> <p>11 A. It is appropriate that it is</p> <p>12 in the IFU.</p> <p>13 Q. Next one is one or more</p> <p>14 revision surgeries may be necessary to</p> <p>15 treat these adverse reactions. You agree</p> <p>16 that that is a risk with a TVT-O;</p> <p>17 correct?</p> <p>18 A. I agree that it is a risk,</p> <p>19 yes.</p> <p>20 Q. And you agree that it's</p> <p>21 appropriate for that to be in the TVT-O</p> <p>22 IFU; correct?</p> <p>23 A. It is appropriate to be in</p> <p>24 the IFU.</p>
<p style="text-align: right;">Page 83</p> <p>1 including acute and/or chronic pain in</p> <p>2 the groin, thigh, leg, pelvic and/or</p> <p>3 abdominal area may occur, you agree that</p> <p>4 that's a risk with a TVT-O device;</p> <p>5 correct?</p> <p>6 A. It is.</p> <p>7 Q. And you agree that it's</p> <p>8 appropriate to put that in the IFU;</p> <p>9 correct?</p> <p>10 A. As stated, yes.</p> <p>11 Q. The next one is recurrence</p> <p>12 of incontinence. That is a risk with a</p> <p>13 TVT-O device; correct?</p> <p>14 A. As with any antiincontinence</p> <p>15 surgery as well.</p> <p>16 Q. So recurrence of</p> <p>17 incontinence is a risk with the TVT-O</p> <p>18 device; correct?</p> <p>19 A. Yes, it is.</p> <p>20 Q. And you think it's</p> <p>21 appropriate that that be in the IFU;</p> <p>22 correct?</p> <p>23 A. It is appropriate.</p> <p>24 Q. Bleeding including</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. The next one is proline mesh</p> <p>2 is a permanent implant that integrates</p> <p>3 into the tissue. You agree with that;</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. And it goes on to say in</p> <p>7 cases in which the proline mesh needs to</p> <p>8 be removed in part or whole significant</p> <p>9 dissection may be required. You agree</p> <p>10 that that is a risk of the TVT-O device;</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. And you agree that that's</p> <p>14 appropriate that physicians be told that</p> <p>15 in the IFU; correct?</p> <p>16 A. As mentioned here in the</p> <p>17 IFU, they mentioned it. It's appropriate</p> <p>18 for it to be here in this IFU.</p> <p>19 Q. Would you think it's</p> <p>20 inappropriate to not have that in the</p> <p>21 IFU?</p> <p>22 MS. GRAFF: Object to form.</p> <p>23 THE WITNESS: Two negatives</p> <p>24 so ...</p>

<p style="text-align: right;">Page 86</p> <p>1 BY MR. ZONIES:</p> <p>2 Q. If that were not in the IFU,</p> <p>3 is that inappropriate?</p> <p>4 MS. GRAFF: Same objection.</p> <p>5 THE WITNESS: I would think</p> <p>6 that the physician who puts in a</p> <p>7 TVT-O going through the anatomy</p> <p>8 through which it goes through,</p> <p>9 removing it would require</p> <p>10 significant dissection or may</p> <p>11 require significant dissection</p> <p>12 depending on the extent that needs</p> <p>13 to be removed, the timing and the</p> <p>14 circumstances.</p> <p>15 BY MR. ZONIES:</p> <p>16 Q. If a company knows that a</p> <p>17 potential adverse reaction associated</p> <p>18 with the use of their medical device is</p> <p>19 that it may need to be removed in whole</p> <p>20 or part requiring significant dissection,</p> <p>21 that's something that should be included</p> <p>22 in an IFU; correct?</p> <p>23 MS. GRAFF: Object to form.</p> <p>24 THE WITNESS: I think it's</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. If a company knew that these</p> <p>2 risks existed, the company should include</p> <p>3 these risks in the IFU; correct?</p> <p>4 MS. GRAFF: Object to form.</p> <p>5 THE WITNESS: "Should" I</p> <p>6 don't know, but they did, so it is</p> <p>7 very appropriate that they placed</p> <p>8 them here.</p> <p>9 BY MR. ZONIES:</p> <p>10 Q. If the company knew that</p> <p>11 these risks existed with the use of their</p> <p>12 device, would it be inappropriate for the</p> <p>13 company to refuse to put these risks in</p> <p>14 the IFU?</p> <p>15 MS. GRAFF: Object to form.</p> <p>16 THE WITNESS: It depends.</p> <p>17 BY MR. ZONIES:</p> <p>18 Q. On?</p> <p>19 A. Severity, relevance,</p> <p>20 clinical relevance, frequency. It</p> <p>21 depends. We can't list every</p> <p>22 complication known to mankind on an IFU;</p> <p>23 and so what is -- the complications that</p> <p>24 are mentioned here are very appropriate</p>
<p style="text-align: right;">Page 87</p> <p>1 very appropriate that it is</p> <p>2 included in this IFU.</p> <p>3 BY MR. ZONIES:</p> <p>4 Q. Are the warnings that we've</p> <p>5 just gone through in the IFU sufficient</p> <p>6 and adequate based on your experience?</p> <p>7 A. Yes, they are.</p> <p>8 Q. Under the next section is</p> <p>9 Other Adverse Reactions. Do you see</p> <p>10 that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. And there it lists seroma,</p> <p>13 urge incontinence, urinary frequency,</p> <p>14 urinary retention, adhesion formation,</p> <p>15 atypical vaginal discharge, exposed mesh</p> <p>16 may cause pain or discomfort to the</p> <p>17 patient's partner during intercourse and</p> <p>18 death. Did I read those correctly?</p> <p>19 A. You read those correctly.</p> <p>20 Q. And those are appropriate</p> <p>21 adverse reactions to include in the IFU;</p> <p>22 correct?</p> <p>23 A. They are appropriate to be</p> <p>24 included in this IFU.</p>	<p style="text-align: right;">Page 89</p> <p>1 to be in this IFU.</p> <p>2 Q. They're appropriate to be in</p> <p>3 the IFU because it informs physicians of</p> <p>4 the potential risks of using the device;</p> <p>5 correct?</p> <p>6 A. These inform the surgeon of</p> <p>7 these potential risks and they're</p> <p>8 appropriately placed in this IFU.</p> <p>9 Q. And they in turn would help</p> <p>10 a physician have an informed consent</p> <p>11 conversation with his or her patient</p> <p>12 about the risks as well; correct?</p> <p>13 A. As you said, I can't be in</p> <p>14 every surgeon's head, but one would by</p> <p>15 looking at these ahead of surgery knowing</p> <p>16 this procedure, they would be more</p> <p>17 enlightened if they had not been at all</p> <p>18 and before they performed their first</p> <p>19 TVT-O that this would be an aid to their</p> <p>20 general body of knowledge and experience</p> <p>21 in order to appropriately inform the</p> <p>22 patient of the risk benefit of a</p> <p>23 particular surgery.</p> <p>24 Q. Having these adverse</p>

<p style="text-align: right;">Page 90</p> <p>1 reactions and risks listed certainly 2 could only benefit the physician in 3 understanding the risks and benefit the 4 physician's patient to understand the 5 risks; correct? 6 MS. GRAFF: Object to form. 7 THE WITNESS: As an 8 addition. 9 BY MR. ZONIES: 10 Q. As additional information 11 for that physician to use when making the 12 determination of whether or not to 13 perform the surgery and having a 14 discussion with their patient about 15 performing the surgery; correct? 16 MS. GRAFF: Objection. 17 THE WITNESS: As stated in 18 this particular brochure for this 19 particular procedure, yes. 20 BY MR. ZONIES: 21 Q. In preparation of your 22 report, Doctor, did you review the TVT-O 23 instructions for use? 24 A. Yes.</p>	<p style="text-align: right;">Page 92</p> <p>1 ahead and mark this as Exhibit 2 2 please? 3 (Whereupon, the court 4 reporter marked Exhibit 2 for 5 identification as of this date.) 6 BY MR. ZONIES: 7 Q. Doctor, you've just been 8 handed Exhibit 2. This is another TVT 9 Obturator IFU and this happens to be an 10 IFU that's listed in your reliance 11 materials. 12 A. Okay. 13 Q. Does this appear to be the 14 IFU that you reviewed in the preparation 15 of your report? 16 A. If it's in my reliance 17 material, chances are it is. I would 18 have to confirm that there's not another 19 IFU that was produced between 2005 and 20 2009. 21 Q. And if you look at the 22 adverse reactions section in this IFU, 23 you'll see that it's significantly 24 shorter than the one we just went</p>
<p style="text-align: right;">Page 91</p> <p>1 Q. When? 2 A. Before my report. 3 Q. Sometime between January and 4 February 2016? 5 A. That would be correct. 6 Q. Do you know which version? 7 Did you review only one IFU? 8 A. I was sent multiple 9 documents on PDFs, in PDF form, and I 10 cannot be sure if it was a variation of 11 -- if there was more than one produced. 12 This I see is the version from 2005. 13 Actually, there's a date of January 2015 14 here and then it says 2005, so I don't 15 know which version I read. 16 Q. In rendering your opinions 17 in the Gomez case, do you know if you 18 read the IFU that would have been in 19 effect when Ms. Gomez had her TVT-O 20 implanted? 21 A. I think I did. I think that 22 was part of the documents that they 23 provided to me. 24 MR. ZONIES: Can you go</p>	<p style="text-align: right;">Page 93</p> <p>1 through; isn't it? 2 MS. GRAFF: Object to form. 3 THE WITNESS: What page are 4 you looking at here? Okay. 5 BY MR. ZONIES: 6 Q. Page 7. 7 A. I agree that the paragraph 8 of adverse reaction in the 2005 version 9 of this IFU is different than the version 10 in 2015 which was Exhibit 1. 11 Q. So in Exhibit 2, Doctor, if 12 you look at it, do you see any indication 13 in the adverse reaction section that 14 Ethicon is informing physicians of the 15 risk of seroma? 16 A. The specific risk of seroma 17 in this paragraph of adverse reaction is 18 not specifically mentioned. 19 Q. Is the risk of urge 20 incontinence mentioned? 21 A. In this IFU, the risk is -- 22 that particular risk is not mentioned. 23 Q. Is urinary frequency 24 mentioned?</p>

<p style="text-align: right;">Page 94</p> <p>1 A. No, it is not mentioned.</p> <p>2 Q. Is urinary retention</p> <p>3 mentioned?</p> <p>4 A. In specific words, no, but</p> <p>5 it does say temporary or permanent lower</p> <p>6 urinary tract obstruction, so that would</p> <p>7 be clinically the same as retention.</p> <p>8 Q. Is adhesion formation</p> <p>9 mentioned?</p> <p>10 A. The word adhesion formation</p> <p>11 is not specifically written as stated,</p> <p>12 but you have foreign body reaction could</p> <p>13 result in extrusion, erosion, fistula</p> <p>14 formation or inflammation. They're all</p> <p>15 precursors of adhesions. This obviously</p> <p>16 contains less words than what is in the</p> <p>17 2015 version.</p> <p>18 Q. And atypical vaginal</p> <p>19 discharge, is that mentioned?</p> <p>20 A. The atypical vaginal</p> <p>21 discharge is not mentioned in this</p> <p>22 particular IFU.</p> <p>23 Wait a minute. Some of</p> <p>24 these adverse reactions are located in</p>	<p style="text-align: right;">Page 96</p> <p>1 maybe not explicitly but implied with</p> <p>2 voiding dysfunction.</p> <p>3 Q. It's an implied warning?</p> <p>4 A. A surgeon should know that</p> <p>5 detrusor instability would cause urgency</p> <p>6 frequency and may cause even urge</p> <p>7 incontinence, so that would be part of</p> <p>8 the general body of knowledge of a</p> <p>9 surgeon who would be implanting a TVT-O</p> <p>10 reading this IFU.</p> <p>11 Q. That's your assumption that</p> <p>12 physicians would know that?</p> <p>13 MS. GRAFF: Object to form.</p> <p>14 Mischaracterizes.</p> <p>15 THE WITNESS: It's in the</p> <p>16 general literature. As with any</p> <p>17 antiincontinence procedure whether</p> <p>18 it's pubovaginal sling, Burch,</p> <p>19 midurethral slings, urgency</p> <p>20 frequency will occur. Detrusor</p> <p>21 instability may occur.</p> <p>22 BY MR. ZONIES:</p> <p>23 Q. Does the 2005 brochure say</p> <p>24 anything about exposed mesh may cause</p>
<p style="text-align: right;">Page 95</p> <p>1 warnings and precautions, so that as I'm</p> <p>2 reading here, there is detrusor</p> <p>3 instability, so there are risks of</p> <p>4 voiding dysfunction in this brochure that</p> <p>5 are maybe not stated verbatim but are the</p> <p>6 equivalent.</p> <p>7 Q. It's more detailed warnings</p> <p>8 in the 2015 IFU?</p> <p>9 A. Well, I'd have to see if the</p> <p>10 word de novo detrusor instability is in</p> <p>11 the 2015 IFU.</p> <p>12 Q. If you look just adverse</p> <p>13 reactions four bullets up, it says as</p> <p>14 with other incontinence procedures, de</p> <p>15 novo detrusor and instability may occur?</p> <p>16 A. Right.</p> <p>17 Q. So there --</p> <p>18 A. And that would go with</p> <p>19 voiding dysfunction. It's just a</p> <p>20 different term. So the fact that the</p> <p>21 term voiding dysfunction is not written</p> <p>22 on the 2005 brochure, de nova detrusor</p> <p>23 instability or urgency frequency, pardon</p> <p>24 me, the urgency frequency is in the 2005</p>	<p style="text-align: right;">Page 97</p> <p>1 pain or discomfort to the patient's</p> <p>2 partner during intercourse?</p> <p>3 A. Let me just make sure. In</p> <p>4 this brochure it is not specifically</p> <p>5 mentioned.</p> <p>6 Q. So you would agree with me,</p> <p>7 Doctor, that when comparing Exhibits 1</p> <p>8 and 2 that the Exhibit 1, 2015 brochure</p> <p>9 certainly has more detail and lists</p> <p>10 additional adverse reactions in it that</p> <p>11 the company feels or felt at this time</p> <p>12 that it should include in the IFU as</p> <p>13 compared to Exhibit 2; correct?</p> <p>14 A. I don't know what the</p> <p>15 company felt as far as feelings, but</p> <p>16 there are more specified or more lists of</p> <p>17 adverse reaction mentioned in the 2015</p> <p>18 brochure than the 2005.</p> <p>19 Q. And certainly it seems like</p> <p>20 your testimony today is is that all of</p> <p>21 the risks in the 2015, those were all</p> <p>22 known in 2005?</p> <p>23 MS. GRAFF: Object to form.</p> <p>24 THE WITNESS: I wouldn't</p>

<p style="text-align: right;">Page 98</p> <p>1 characterize it that way. I think 2 most of the major risks associated 3 with this procedure as far as 4 midurethral slings, TVT-O, I think 5 most of the severe risks were 6 known in 2005. 7 BY MR. ZONIES: 8 Q. And you agree that when we 9 went through the 2015 IFU, you agree that 10 these warnings and adverse reactions were 11 all reasonable to include in the IFU; 12 correct? 13 A. I think it was reasonable 14 for a company to include these risks in 15 an IFU. 16 Q. And are there some risks in 17 the 2015 IFU that you believe weren't 18 well-known in 2005? 19 A. I'm not sure that any of 20 these risks weren't known in 2005. There 21 are not too many studies that have 22 reported on partner dyspareunia 23 specifically and I can't recall if and 24 when those started to appear. Permanent</p>	<p style="text-align: right;">Page 100</p> <p>1 MS. GRAFF: Object to form. 2 THE WITNESS: Should not be 3 in a patient brochure? 4 BY MR. ZONIES: 5 Q. Yes. 6 A. There's nothing in here that 7 should not be in a patient brochure in 8 these adverse reactions. 9 MR. ZONIES: Why don't we 10 take a break? 11 (Whereupon, a brief recess 12 was held from 3:42 to 3:50 p.m. 13 Mr. Bentley left the deposition.) 14 BY MR. ZONIES: 15 Q. Doctor, before we broke we 16 were looking at Exhibit 1 which is the 17 2015 IFU and the adverse events that are 18 listed there in that IFU, would it be 19 appropriate to list those adverse events 20 in a patient brochure as well? 21 MS. GRAFF: Object to form. 22 THE WITNESS: I wouldn't 23 know what is appropriate or not in 24 the design of a patient brochure</p>
<p style="text-align: right;">Page 99</p> <p>1 stitches in the vagina for any reason can 2 cause pain to the partner, so it's not a 3 long shot to think that a polypropylene 4 mesh could cause pain to the partner. It 5 was known with sacrocolpopexy, so it's 6 not far reached that this could have been 7 known in 2005. 8 Q. And they added that warning 9 in 2015; correct? 10 MS. GRAFF: Objection. 11 Lacks foundation. 12 BY MR. ZONIES: 13 Q. According to Exhibit 1? 14 MS. GRAFF: Same objection. 15 THE WITNESS: According to 16 Exhibit 1, these are the lists of 17 things that appear in the IFU and 18 it's different than 2005. 19 BY MR. ZONIES: 20 Q. Is there anything on Exhibit 21 1 in the adverse reaction section that we 22 were just looking at that you think 23 shouldn't have been included in a patient 24 brochure?</p>	<p style="text-align: right;">Page 101</p> <p>1 to inform a patient. 2 BY MR. ZONIES: 3 Q. You don't have an opinion on 4 whether or not that should be included in 5 a patient brochure? 6 A. And to what detail patient 7 brochures are informative, marketing and 8 do not substitute for informed consent 9 and a discussion with the doctor. So 10 what is appropriate to be put in a 11 patient brochure just like the ads on TV 12 we see whether it's for drugs or any 13 product, there's always a disclaimer and 14 to talk to your doctor. Patient 15 brochures are the same way. 16 Q. So do you have an opinion on 17 whether or not the information in the 18 adverse reactions section of the 2015 19 IFU, whether or not that information 20 should have been included in a patient 21 brochure? 22 A. Should have? 23 Q. Yes. Do you have an opinion 24 on that?</p>

<p style="text-align: right;">Page 102</p> <p>1 A. I think it doesn't need to 2 in part or total modified so that the 3 patient can understand some of it, but 4 the brochure is to start a conversation 5 and/or to give a patient to think about 6 things and then come back and then 7 discuss it again. From the patient 8 brochures, they can do research on the 9 Internet if they have a computer, talk to 10 friends, and then come back, but what a 11 patient understands to go to surgery 12 would more rely on the discussion that 13 they would have had with their surgeon 14 who is actually going to perform the 15 surgery.</p> <p>16 Q. But don't you think it would 17 be helpful for a patient to have those 18 adverse reactions in front of them and 19 say, doctor, can you tell me what is a 20 seroma and what's the risk of that and 21 what might the potential adverse outcome 22 be?</p> <p>23 MS. GRAFF: Object to form. 24 THE WITNESS: It depends on</p>	<p style="text-align: right;">Page 104</p> <p>1 form. 2 THE WITNESS: They're not on 3 the bottle, just like they're not 4 on television. 5 BY MR. ZONIES: 6 Q. Well, you were talking about 7 on television where they list the adverse 8 events at the end of an advertisement; 9 right? 10 A. It is an absolute small 11 blurb sometimes not even mentioned but it 12 says talk to your doctor, for more 13 information talk to your doctor. So to 14 list certain complications on a patient 15 brochure I think is very appropriate 16 because it starts the discussion. 17 Do every potential risks 18 known to mankind for every procedure need 19 to be listed on a patient brochure? Then 20 the answer is probably not. It would 21 have a counter-effective negative impact 22 of that brochure. It wouldn't start the 23 discussion. Any surgical brochure needs 24 to look at risk versus benefits. So</p>
<p style="text-align: right;">Page 103</p> <p>1 the adverse event. If we gave 2 adverse event for a bottle of 3 Tylenol, it may be that nobody 4 would ever take their Tylenol 5 medicine, nobody would ever take 6 their blood pressure medicine. 7 Although it saves lives, there are 8 some serious risks associated with 9 blood pressure medicine. 10 So it's a fine balance to be 11 informative and to start a 12 discussion with a patient 13 brochure, but again it doesn't 14 substitute for all of the risks 15 and conversations that need to be 16 had with the implanting physician. 17 BY MR. ZONIES: 18 Q. Well, you know for example 19 on a bottle of Tylenol or blood pressure 20 medication the adverse effects and 21 warnings and contraindications are fairly 22 lengthy and detailed even for the 23 patients; right? 24 MS. GRAFF: Objection to</p>	<p style="text-align: right;">Page 105</p> <p>1 these are the complications, but talk to 2 your doctor, it's permanent. 3 Q. And I'm not talking about 4 every complication under the sun. I'm 5 just talking about the ones that are 6 listed in Exhibit 1 and I believe you 7 testified earlier that having these 8 adverse reactions in a patient brochure 9 would be reasonable. Correct? 10 A. I'd have to have my 11 deposition re-read to that, but certain 12 risks and adverse reactions to be put in 13 in a patient brochure are reasonable. 14 Are they mandatory? Are they necessary? 15 What does the government or the FDA 16 require? That I can't tell you. 17 Q. And you've said that a 18 number of times. You don't know what the 19 requirements, if any, are that drive what 20 needs to be included in an IFU; correct? 21 A. I don't know the specific 22 regulation of what is needed, but I've 23 seen many IFUs and that gives me 24 experience and knowledge and that's where</p>

<p style="text-align: right;">Page 106</p> <p>1 I draw my conclusions from.</p> <p>2 Q. And it's the same with</p> <p>3 patient brochures. You have no idea what</p> <p>4 is or is not required in patient</p> <p>5 brochures; correct?</p> <p>6 A. I don't know of any</p> <p>7 regulation that regulates patient</p> <p>8 brochures.</p> <p>9 Q. One of the adverse reactions</p> <p>10 in Exhibit -- let me go ahead and -- one</p> <p>11 of the adverse reactions in Exhibit 2</p> <p>12 that you have in front of you, Doctor, is</p> <p>13 transitory local irritation at the wound</p> <p>14 site and a transitory foreign body</p> <p>15 response. Do you see that one?</p> <p>16 A. I do see that.</p> <p>17 Q. Would it have been -- strike</p> <p>18 that.</p> <p>19 In drafting your expert</p> <p>20 report, Doctor, do you recall seeing any</p> <p>21 internal Ethicon emails about that</p> <p>22 language about a transitory foreign body</p> <p>23 response?</p> <p>24 A. I remember seeing</p>	<p style="text-align: right;">Page 108</p> <p>1 BY MR. ZONIES:</p> <p>2 Q. So do you recall reviewing</p> <p>3 any emails or documents from the</p> <p>4 associate medical director at Ethicon by</p> <p>5 the name of Meng Chen?</p> <p>6 A. I remember that name. I</p> <p>7 remember viewing some documents, yes.</p> <p>8 Q. And do you remember that</p> <p>9 that associate medical director Doctor</p> <p>10 Chen had informed her superiors that she</p> <p>11 received numerous phone calls from women</p> <p>12 who had had a TVT device implanted and</p> <p>13 the problems they were describing were</p> <p>14 not at all transitory problems?</p> <p>15 MS. GRAFF: Object to form.</p> <p>16 THE WITNESS: I don't recall</p> <p>17 that specific information, but</p> <p>18 what you're telling me is that</p> <p>19 these women have a problem that is</p> <p>20 not transient. This talks about a</p> <p>21 transitory foreign body response</p> <p>22 which is an immune response or an</p> <p>23 inflammatory response to the mesh</p> <p>24 with giant foreign body cells and</p>
<p style="text-align: right;">Page 107</p> <p>1 documentation pertaining to that. I</p> <p>2 cannot recall if they were in the form of</p> <p>3 a letter, of an email or internal</p> <p>4 research documentation that Ethicon would</p> <p>5 have had at this time.</p> <p>6 Q. If one of Ethicon's</p> <p>7 associate medical directors when</p> <p>8 reviewing that language had informed her</p> <p>9 superiors that in her experience in the</p> <p>10 report she was receiving from women who</p> <p>11 had had TVT device implanted the foreign</p> <p>12 body response was not at all transitory,</p> <p>13 is that something that you would have</p> <p>14 wanted to know prior to drafting your</p> <p>15 expert witness report?</p> <p>16 MS. GRAFF: Object to form.</p> <p>17 THE WITNESS: So you're</p> <p>18 saying that this particular person</p> <p>19 would have known from women that</p> <p>20 their own -- that they had a</p> <p>21 foreign body response? How would</p> <p>22 a particular woman know that she</p> <p>23 has a foreign body response and</p> <p>24 not anything else happening?</p>	<p style="text-align: right;">Page 109</p> <p>1 that is at the, you know, cellular</p> <p>2 level, microscopical level.</p> <p>3 Now, what I read in this</p> <p>4 brochure is you can have a</p> <p>5 transitory foreign body response</p> <p>6 may occur, period; this response</p> <p>7 could result in extrusion,</p> <p>8 erosion, fistula formation or</p> <p>9 inflammation. Those complications</p> <p>10 of extrusion, erosion, fistula</p> <p>11 formation or inflammation are</p> <p>12 listed in these adverse reactions.</p> <p>13 MS. GRAFF: Just before you</p> <p>14 go on, that's not a brochure; it's</p> <p>15 an IFU.</p> <p>16 THE WITNESS: Pardon me. In</p> <p>17 this IFU.</p> <p>18 BY MR. ZONIES:</p> <p>19 Q. And you would agree those</p> <p>20 are not transitory outcomes; correct?</p> <p>21 A. Correct, and they're</p> <p>22 separate than a foreign body response or</p> <p>23 they may be separate than a foreign body</p> <p>24 response.</p>

<p style="text-align: right;">Page 110</p> <p>1 Q. So if Ethicon's associate 2 medical director had described the report 3 she was receiving from women who had a 4 device as not transitory, you would agree 5 that that is -- that these outcomes are 6 not transitory outcomes; correct? 7 MS. GRAFF: Object to form 8 when you say these outcomes. 9 THE WITNESS: What outcomes? 10 BY MR. ZONIES: 11 Q. The outcomes right in that 12 sentence that you described. 13 MS. GRAFF: Same objection. 14 THE WITNESS: The extrusion, 15 erosion, fistula formation or 16 inflammation if they occur will 17 continue to occur until treatment 18 is initiated and then will 19 retrospectively be transient 20 because they will stop occurring. 21 BY MR. ZONIES: 22 Q. Once treatment is received; 23 correct? 24 A. If a particular patient has</p>	<p style="text-align: right;">Page 112</p> <p>1 materials as Exhibit 4. Okay? Okay? 2 Yes? 3 A. Yes. 4 (Whereupon, the court 5 reporter marked Exhibit 4 for 6 identification as of this date.) 7 BY MR. ZONIES: 8 Q. You brought with you today a 9 CV that is an updated CV; is that right? 10 A. Updated from the version my 11 attorney had produced. 12 Q. And what is updated in your 13 new CV? 14 MS. GRAFF: Do you have one 15 that you can hand to her? I can 16 hand mine to her, but I think you 17 have two. 18 MR. ZONIES: Let me go ahead 19 and mark as Exhibit 5 the CV you 20 brought with you today. 21 (Whereupon, the court 22 reporter marked Exhibits 3 and 5 23 for identification as of this 24 date.)</p>
<p style="text-align: right;">Page 111</p> <p>1 an extrusion or an erosion, once the 2 extrusion or erosion has been resolved, 3 then that particular complication has an 4 end point to it and thus will be 5 considered transient. 6 Q. You're saying that the 7 extrusion, exposure or fistula if 8 untreated it certainly is not transient; 9 correct? 10 A. Usually not. 11 Q. Doctor, in your last 12 deposition we marked your report as 13 Exhibit 1-A and so in this deposition I 14 would again like to mark the report as 15 Exhibit 1-A. Okay? 16 A. If you say so. 17 (Whereupon, the court 18 reporter marked Exhibit 1-A for 19 identification as of this date.) 20 BY MR. ZONIES: 21 Q. And then in the last 22 deposition we marked as Exhibit 4 your 23 reliance materials for your report, so 24 again I'd like to mark the reliance</p>	<p style="text-align: right;">Page 113</p> <p>1 BY MR. ZONIES: 2 Q. Doctor, we've had marked as 3 Exhibit 3 the CV that was provided to us 4 with your report and then marked as 5 Exhibit 5 is the CV that you brought with 6 you today. So can you tell me the 7 difference between the two, if any? 8 A. One has my entire address 9 blocked off by a black marker of some 10 sort. The thing that is different is 11 some of the font and the fact that FPMRS 12 or Female Pelvic Medicine and 13 Reconstructive Surgery is added 14 underneath my name. 15 Q. To Exhibit 5? 16 A. To Exhibit 5 and it was not 17 on Exhibit 3. The Exhibit 3 has the 18 address and phone number blocked off, 19 whatever it was. 20 Q. So aside from what we call 21 the redaction of your address, the only 22 update to your CV as reflected in Exhibit 23 5 is the letters reflecting your 24 certification for female pelvic floor; is</p>

<p style="text-align: right;">Page 114</p> <p>1 that right?</p> <p>2 A. As I'm continuing to just go</p> <p>3 through it, that looks like it is a</p> <p>4 correct statement.</p> <p>5 Q. Now, Doctor, you brought</p> <p>6 with you today as Exhibits 1 and 2,</p> <p>7 marked in the original deposition as</p> <p>8 Exhibits 1 and 2 and now for this</p> <p>9 deposition we'll mark them as Exhibits 6</p> <p>10 and 7.</p> <p>11 (Whereupon, the court</p> <p>12 reporter marked Exhibits 6 and 7</p> <p>13 for identification.)</p> <p>14 BY MR. ZONIES:</p> <p>15 Q. I'm just write TVT-O under</p> <p>16 those two new stickers.</p> <p>17 MS. GRAFF: Just for the</p> <p>18 record, these are being marked and</p> <p>19 I assume will go with the court</p> <p>20 reporter today. They're going to</p> <p>21 need to come back to the Doctor</p> <p>22 because they're hers.</p> <p>23 MR. ZONIES: I'll leave that</p> <p>24 between you and you.</p>	<p style="text-align: right;">Page 116</p> <p>1 by Butler Snow. Some of the articles</p> <p>2 that are in here are different than the</p> <p>3 USB port that you were given this</p> <p>4 morning. The wrong article was placed in</p> <p>5 there in certain cases or it's the right</p> <p>6 author but not the correct authored paper</p> <p>7 for that particular reference, and at the</p> <p>8 end there are some expert reports that I</p> <p>9 don't think I have -- that were not part</p> <p>10 of my reliance list. Pardon me. They're</p> <p>11 included here but they're not part of my</p> <p>12 reliance list.</p> <p>13 Q. And by that you mean in</p> <p>14 Binder 2 which has been marked in this</p> <p>15 deposition as Exhibit 7 there is what's</p> <p>16 entitled on the tab 2015 Margolis CER</p> <p>17 dated 4/24/15 which appears to be</p> <p>18 entitled Expert Report of Michael Thomas</p> <p>19 Margolis in the Rameriz Case; is that</p> <p>20 right?</p> <p>21 A. That's the title of that</p> <p>22 report.</p> <p>23 Q. And this is a report that</p> <p>24 you actually did not receive and rely</p>
<p style="text-align: right;">Page 115</p> <p>1 (Whereupon, the court</p> <p>2 reporter marked Exhibits 6 and 7</p> <p>3 for identification as of this</p> <p>4 date.)</p> <p>5 BY MR. ZONIES:</p> <p>6 Q. These two binders reflect</p> <p>7 materials that you brought with you today</p> <p>8 that originally you understood were to be</p> <p>9 the reference materials listed in your</p> <p>10 reliance; is that correct?</p> <p>11 A. That was the understanding</p> <p>12 and it was provided to me by Butler Snow</p> <p>13 Thursday of last week which was a week</p> <p>14 ago, seven days ago.</p> <p>15 Q. Do you have copies of most</p> <p>16 of this scientific literature at your</p> <p>17 office or at your home as well that you</p> <p>18 used in writing your report?</p> <p>19 A. A lot of those came via</p> <p>20 email and some of those I've researched</p> <p>21 myself on the computer, so I don't know</p> <p>22 if I have an integral copy of everything</p> <p>23 that's in there. Certainly what's in</p> <p>24 there has some errors. It was provided</p>	<p style="text-align: right;">Page 117</p> <p>1 upon in drafting your expert report?</p> <p>2 A. I don't recall it.</p> <p>3 Q. And the same could be said</p> <p>4 of the Prolift Garely report in your</p> <p>5 binder; correct? The one that has the</p> <p>6 pictures in it?</p> <p>7 A. That one I'm not as sure.</p> <p>8 Q. Did you review any</p> <p>9 Plaintiff's expert reports on the TVT-O?</p> <p>10 A. Not that I recall at this</p> <p>11 moment.</p> <p>12 Q. Did you perform any</p> <p>13 independent medical literature research</p> <p>14 on the TVT-O?</p> <p>15 A. I was not part of a research</p> <p>16 project, but I did run a pub med on it.</p> <p>17 Q. Tell me what that pub med</p> <p>18 search was?</p> <p>19 A. I looked for TVT-O versus</p> <p>20 transobturator or TOT approach, I looked</p> <p>21 for the Cochrane Review on suburethral</p> <p>22 sling, pubovaginal sling, Burch, so</p> <p>23 looked at a lot of articles.</p> <p>24 Q. One of the articles that is</p>

Page 118	Page 120
<p>1 not on your reliance list that has to do 2 with the TVT-O is a study by Teo -- 3 T-E-O. Do you recall reviewing that 4 study at all?</p> <p>5 A. That name sounds familiar, 6 yes.</p> <p>7 Q. It's a study where they 8 stopped the study early because of the 9 pain associated with the TVT-O procedure. 10 Do you recall that?</p> <p>11 A. I would have --</p> <p>12 MS. GRAFF: Object to form.</p> <p>13 THE WITNESS: -- to look at 14 that article. I vaguely remember, 15 but in order to refresh my mind 16 and comment on it, you'd have to 17 produce the article.</p> <p>18 BY MR. ZONIES:</p> <p>19 Q. In fact, there are a couple 20 of studies that were stopped early, a 21 couple of studies -- strike that.</p> <p>22 In fact, there were more 23 than one study on the TVT-O device that 24 was stopped early because the</p>	<p>1 appropriate to continue using TVT-O 2 devices. You don't discuss those in the 3 body of your report; correct?</p> <p>4 A. I don't discuss those in the 5 body of my report because those studies 6 never achieved statistical significance 7 and the definition of pain, there will be 8 pain associated with any procedure, so, 9 the definition of pain in some of these 10 articles was not clearly defined, was 11 that pain immediately, 24, 72 hours. 12 Most of the metaanalysis that included 13 the in to out or TVT-O do not report a 14 substantial amount of groin or inner 15 thigh pain going beyond the normal 16 postoperative period.</p> <p>17 Q. You did choose certain 18 studies to include in your report; 19 correct?</p> <p>20 A. I did.</p> <p>21 Q. And did you chose studies 22 that would support your opinion to 23 include in the body of your report?</p> <p>24 A. I included studies that I</p>
Page 119	Page 121
<p>1 investigators felt that continuing to use 2 the TVT-O device was not appropriate 3 given the amount of pain that women were 4 experiencing in the study. Do you recall 5 any of the studies like that?</p> <p>6 MS. GRAFF: Object to form.</p> <p>7 THE WITNESS: I would have 8 to re-review what you're telling 9 me and why in order to make an 10 opinion, but if we look at the 11 thousands and thousands of TVT-Os, 12 transobturator approaches that 13 have been performed, that's not 14 what's in the body of the entire 15 medical review comparing in and 16 out TVT-O versus out to in TOT 17 versus retropubic. That is not 18 the experience of the body of 19 literature.</p> <p>20 BY MR. ZONIES:</p> <p>21 Q. And you actually in the body 22 of your report, you don't discuss any of 23 the studies that were halted because the 24 investigators felt it was no longer</p>	<p>1 would rely on and the studies that -- the 2 Teo study that you have mentioned, I did 3 not include it because I didn't consider 4 it for my report. I didn't rely on it.</p> <p>5 Q. I noticed in your report 6 that you have a substantial amount of 7 Prolift literature in your expert report. 8 Is that right?</p> <p>9 MS. GRAFF: Object to the 10 form.</p> <p>11 THE WITNESS: I didn't 12 calculate the proportions of 13 Prolift versus Prolift+M, but yes.</p> <p>14 BY MR. ZONIES:</p> <p>15 Q. When you were drafting this 16 report, did you start with your Hammons 17 report and make edits to the Hammons 18 report?</p> <p>19 A. I used part of the Hammons 20 report as a basis as this report is a 21 case specific report.</p> <p>22 Q. And what does that mean to 23 you that it's "a case specific report"?</p> <p>24 A. That I was asked to perform</p>

<p style="text-align: right;">Page 122</p> <p>1 an analysis of Mrs. Gomez' case. 2 Q. We've been supplied with 3 three invoices for your work on the Gomez 4 case. Does that sound accurate? 5 A. There are three invoices 6 since mid December of 2015. 7 Q. And do those invoices 8 reflect your work only on this expert 9 report that has been marked as Exhibit 10 1-A in this case? 11 A. Not necessarily. They have 12 sent some other documentation from 13 Ethicon, from the company, videos, live 14 surgery video. 15 Q. And in those invoices, in 16 the last invoice, I believe it said that 17 you had approximately 82 hours of work on 18 this expert report in the month of 19 February. Does that make sense? 20 A. Well, if I could see the 21 report. 22 MS. GRAFF: I can show it to 23 her on my iPad. 24 MR. ZONIES: Would you do</p>	<p style="text-align: right;">Page 124</p> <p>1 preparing my report. 2 Q. And does that also include 3 the actual drafting of your report? 4 A. That does. 5 Q. How many hours did you spend 6 in February that you billed for? 7 A. Total? 8 Q. Yes. 9 A. For everything? It's 10 written up here. It says 81.72 hours. 11 Q. So were you also practicing 12 medicine in the month of February? 13 A. Of course. 14 Q. And how much time per week 15 do you spend in the office in a month 16 like February this year? 17 A. Office and OR, about 60 18 hours a week now. 19 Q. And is it your testimony 20 that in the month of February you spent 21 about 60 hours a week in the office and 22 OR? 23 A. That sounds about right. 24 That's my average.</p>
<p style="text-align: right;">Page 123</p> <p>1 that? That would be great. 2 MS. GRAFF: February? 3 MR. ZONIES: Yeah. It's the 4 last one. I think there was three 5 of them, so it was the last one 6 that was issued. 7 BY MR. ZONIES: 8 Q. I don't have a hard copy, 9 Doctor, so Counsel has agreed to pull it 10 up on her iPad. 11 MS. GRAFF: I have one dated 12 March 4. 13 THE WITNESS: That would be 14 the one. 15 BY MR. ZONIES: 16 Q. Do you have that invoice in 17 front of you, Doctor? 18 A. I do. 19 Q. And what does that invoice 20 reflect? 21 A. That reflects the time I 22 spent reviewing documents from Ethicon or 23 sent by, pardon me, sent by Butler Snow 24 and also review of the literature in</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. And so in addition to that 2 time in February you spent an additional 3 80 hours working on this report? 4 A. If that's what the record 5 shows. I keep accurate records. The 6 answer would be yes. 7 Q. How do you keep those 8 records? 9 A. Well, when I sit down to 10 read something that is provided by Butler 11 Snow as they have provided the documents, 12 I look at the clock, and if I stand up to 13 do something else, I look at my watch and 14 notice how much time I spent, and then if 15 I come back to it I re-note the time and 16 then I bundle it up for each day. 17 Q. Could I see that iPad? 18 A. Sure. 19 Q. Thank you. 20 MR. ZONIES: Is that okay? 21 MS. GRAFF: Yes. 22 BY MR. ZONIES: 23 Q. So your invoice for the 24 Gomez case from February 1st, 2016</p>

<p style="text-align: right;">Page 126</p> <p>1 through February 29th, 2016 you say that 2 you spent a total of 81.72 hours working 3 on the Gomez matter. Is that accurate? 4 A. On matters that are 5 generally with the Gomez case, yes. 6 Q. And what do you mean by 7 that? You seem a little concerned that 8 it wasn't all for Gomez. 9 A. There may be some materials 10 that I may be viewing -- I may have 11 viewed in February that may also be 12 useful for a further case down the road, 13 so those of kind of background matter. 14 Q. Have you been asked to do 15 other cases down the road? 16 A. No, not yet. It has been 17 suggested, but I have not received any 18 documentation. 19 Q. And it says that you billed 20 at \$450 per hour for those 81.72 hours 21 and so you're requesting payment of 22 \$36,774 for your work in the month of 23 February on this case; correct? 24 A. If that's indicated there, I</p>	<p style="text-align: right;">Page 128</p> <p>1 edit certain things so that he could have 2 it and have to email the file to him so 3 he would have it on February 29th. And 4 so he is much more computer savvy than I 5 am. I'm a better doctor than a computer 6 technician. So this was at 11:00 7 something, 11:30 something and 11:50 8 something at night. 9 Q. In your report, Doctor, you 10 say that mesh exposures typically appear 11 within the first few months to one or two 12 years postoperatively. Is that your 13 personal experience as well? 14 A. That's my personal 15 experience and I have references in the 16 literature as well. 17 Q. Have you ever treated an 18 exposure for TVT-O that occurred beyond 19 two years? 20 A. Not that I can recall. 21 MR. ZONIES: Why don't we go 22 ahead and take a break. 23 (Whereupon, a brief recess 24 was held from 4:26 p.m. to 4:32</p>
<p style="text-align: right;">Page 127</p> <p>1 will trust that you read it right. 2 Q. You break it down, your 3 work, by the day that you did the work 4 and then a description of what you did; 5 is that right? 6 A. They have asked me to do so. 7 Q. And it says here that you 8 had a 34-minute phone call with Attorney 9 Rosenblatt on the 27th of February; 10 correct? 11 A. If that's what it says and 12 that's what you're reading, I would agree 13 to it. 14 Q. And then you had three 15 telephone calls, one of six minutes, one 16 of seven minutes and one of 14 minutes 17 with Mr. Rosenblatt on February 29th as 18 well? 19 A. Yes, sir. That was very 20 late in the evening. 21 Q. Did you feel crunched for 22 time when getting your report out? 23 A. That wasn't it. It was a 24 computer -- trying to get my computer to</p>	<p style="text-align: right;">Page 129</p> <p>1 p.m.) 2 BY MR. ZONIES: 3 Q. Doctor, earlier we were 4 talking about when you made the change 5 from using the TVT-O to the T-sling. Do 6 you recall that conversation? 7 A. I recall, yes. 8 Q. Can you tell me why you 9 stopped using the TVT-O? 10 A. Part of it was a question of 11 price. Reusable needle that could be 12 re-sterilized was a cost conservative 13 measure for the hospital. The other part 14 was going out to in for me for my 15 preference and I'd been using the Prolift 16 at the time, and it was just a 17 continuation of what I experienced. So 18 it's a personal preference for that 19 particular and as well for me teaching 20 the residents, that made sense. 21 Q. So it may be up to six years 22 since you've used a TVT-O? 23 A. I wouldn't say that because 24 Apple Hill still continued to use TVT-O</p>

<p style="text-align: right;">Page 130</p> <p>1 and when I would bring patients, until 2 they went to the Obtryx sling and I 3 didn't know why they went and they 4 changed, but here you have to use what 5 the hospital buys, so I am, you know, 6 limited to their options. 7 Q. Well, earlier you testified 8 that it may have been 2010, 2011 when you 9 switched over to the T-Sling; correct? 10 A. No. It was before that. 11 Q. Okay. So -- 12 A. That was when I switched 13 from Prolift+M to the Restorelle 14 transvaginal mesh. 15 Q. That's right. So prior to 16 2010, sometime prior to 2010 you switched 17 primarily to the T-Sling for your stress 18 urinary incontinence procedures? 19 A. Correct. 20 Q. And now in 2016, so six or 21 so years later, you're still using only 22 the T-Sling; correct? 23 A. For now. 24 Q. So over the past six years</p>	<p style="text-align: right;">Page 132</p> <p>1 A. I can't tell you. 2 Q. That's where it gets a 3 little fuzzy? 4 A. As far as the actual device 5 used, yes. 6 Q. Did you have a sort of 7 breakdown on how often you would use 8 retropubic or obturator? 9 A. I am doing more retropubics 10 now than I was. I would say that I'm 11 doing five to ten percent retropubic and 12 the rest transobturator. 13 Q. That's now? Is that what 14 you said? 15 A. In the last year or so I've 16 done more retropubics, so I'm probably at 17 ten percent; but if you look at before, 18 it varies. It varies. I'm in solo 19 practice, and so depending on the 20 patient, her type of incontinence, her 21 prior surgery and all, I will evaluate 22 and decide which approach I use. 23 Q. So the best information you 24 can give me on the last time you may have</p>
<p style="text-align: right;">Page 131</p> <p>1 you haven't implanted a TVT-O? 2 A. No, I wouldn't say that 3 because I practice at different centers 4 and Apple Hill still used TVT-Os up to a 5 certain point which was more recent. So 6 while I was doing T-Sling, transobturator 7 and retropubic at Memorial Hospital, 8 Apple Hill had a different brand of sling 9 and it carried the TVT-O Gynecare for 10 sometime even after I started to do 11 T-Sling at Memorial Hospital, so I can't 12 tell you when they switched to Obtryx and 13 then I had to use what they had. 14 Q. Well, is it fair to say that 15 in the past year you haven't implanted a 16 TVT-O? 17 A. That would be safe to say. 18 Q. How about would it be safe 19 to say in the past two years it's 20 unlikely that you've implanted a TVT-O? 21 A. Two years, yes. 22 Q. How about in the past three 23 years it's unlikely that you implanted a 24 TVT-O?</p>	<p style="text-align: right;">Page 133</p> <p>1 used a TVT-O is maybe sometime three 2 years ago? 3 A. Yeah, three to four years 4 ago. That would be an estimate. 5 Q. Do you have any plans or 6 have you asked any of the hospitals to 7 stock TVT-O? 8 A. To restock it? Not yet; and 9 the reason I say that is there are many 10 sling companies that have decided not to 11 continue making their devices and that 12 includes the T-Sling. So I am currently 13 looking at different companies and 14 different devices. 15 Q. And when you're doing that 16 analysis, what are you looking at? What 17 characteristics of the slings are you 18 looking at to make your decision? 19 A. I am looking at a mesh that 20 would have sufficient pore size that 21 won't roll onto itself easily, I'm not 22 looking at mini slings quite yet, I'm 23 waiting for more data to come out, a mesh 24 that could be used retropubic and</p>

<p style="text-align: right;">Page 134</p> <p>1 transobturator, past performance of the 2 mesh, studies, so I'm looking at a lot of 3 things. 4 Q. Have you seen photographs of 5 the TVT mesh under stress that reflected 6 it deforming and fraying and roping and 7 curling? 8 A. I have seen those pictures, 9 yes, laboratory pictures where they have 10 stretched it, you know, beyond its normal 11 physiological use. 12 Q. And what do you think normal 13 physiological use is? 14 A. Less than what they show in 15 those pictures and it depends on the 16 reports. 17 Q. Do you have a sense of how 18 many newtons for example would be normal 19 load for a sling mesh? 20 A. The reports vary between 21 Ostergard and Ozod who has published his 22 doctoral thesis on it and it looks like 23 with the LaPlace law of tension there's 24 about ten times less the force truly</p>	<p style="text-align: right;">Page 136</p> <p>1 collapsing of pore size or deformation of 2 mesh associated with difficult sheath 3 removal? 4 MS. GRAFF: Object to form. 5 THE WITNESS: I don't know 6 if the pore size were measured 7 after the difficulty of removing 8 the sheaths or not. As far as 9 numerous, numerous depends on the 10 denominator. So ten cases out of 11 12 is a high number; ten cases out 12 of 12 million would not. 13 BY MR. ZONIES: 14 Q. And in your investigation of 15 this issue and in drafting your expert 16 report, do you have a sense of how often 17 those reports were coming in based on the 18 numerator and denominator? 19 MS. GRAFF: Object to form. 20 THE WITNESS: I did not have 21 a denominator. 22 BY MR. ZONIES: 23 Q. In addition to the ten 24 TVT-Os that we had discussed that you</p>
<p style="text-align: right;">Page 135</p> <p>1 applied to the hiatus than was previously 2 thought intraabdominal pressure by 3 Ostergard. 4 Q. Did you ever experience 5 difficulty removing the sheaths with a 6 TVT-O? 7 A. No, I have not. 8 Q. Were you provided with any 9 documents or information demonstrating 10 that Ethicon had received numerous 11 complaints of difficulty removing the 12 sheaths with a TVT-O? 13 A. I have. 14 Q. And you would agree that if 15 there's difficulty removing the sheath 16 that that can apply pressure to the mesh 17 that might collapse the pore size; 18 correct? 19 A. It just depends. If the 20 mesh gets hung on the tissue, on the 21 patient's tissue, then that may not 22 affect the mesh. 23 Q. And have you seen any 24 evidence or documents discussing</p>	<p style="text-align: right;">Page 137</p> <p>1 partially removed, have you treated any 2 other complications with TVT-O meshes? 3 A. Not that I recall. 4 Q. You have, however, treated 5 an erosion or more than one erosion with 6 a TVT-O mesh? 7 A. Yes, and out to in, TOT as 8 well. 9 Q. Doctor, do you have a sense 10 of in these binders that you brought with 11 you today, do you have a sense of which 12 articles you independently found as 13 compared to the ones that were provided 14 to you? 15 A. Not at this minute, no. 16 Q. Do you rely for your expert 17 opinion on deLeval and Waltregny's early 18 first studies for TVT-O? 19 A. I'll have to take a look at 20 the reliance list here. I know that 21 those names are in my reliance list and 22 one is the deLeval that I have is a 2009, 23 the Waltregny is 2006. So how early do 24 you want me to go with TVT-O?</p>

<p style="text-align: right;">Page 138</p> <p>1 Q. Do you recall in reviewing</p> <p>2 the materials for preparation of your</p> <p>3 expert report reviewing a memorandum</p> <p>4 written by a clinical investigator about</p> <p>5 how deLuval was performing his</p> <p>6 experiments with the TVT-O when it was</p> <p>7 first being created?</p> <p>8 MS. GRAFF: Object to form.</p> <p>9 THE WITNESS: I do not know</p> <p>10 how he performed as you say</p> <p>11 experiments.</p> <p>12 BY MR. ZONIES:</p> <p>13 Q. You never saw a memorandum</p> <p>14 that was prepared for Ethicon discussing</p> <p>15 how Doctor deLuval was potentially</p> <p>16 illegally creating devices to test the</p> <p>17 TVT-O methodology?</p> <p>18 MS. GRAFF: Object to form.</p> <p>19 THE WITNESS: I don't know</p> <p>20 about any illegality and what's</p> <p>21 legal in Liege versus, you know,</p> <p>22 America and what's legal or not</p> <p>23 legal for experiments and</p> <p>24 experiments in whom and in what,</p>	<p style="text-align: right;">Page 140</p> <p>1 Q. Do you know if they would</p> <p>2 have shown up on your reliance even if</p> <p>3 you didn't use them or read them?</p> <p>4 A. If these are documents --</p> <p>5 I'd have to go through what they have</p> <p>6 provided me, but this here is</p> <p>7 ETH-MESH-00388485. I do not know what</p> <p>8 this corresponds to and on what has been</p> <p>9 given to me has the word PDF dot a few</p> <p>10 zeros and then some numbers, but it</p> <p>11 doesn't look like this.</p> <p>12 Q. It sounds to me like a lot</p> <p>13 of the materials were provided to you on</p> <p>14 thumb drives; is that right?</p> <p>15 A. Yes. That's what I mean by</p> <p>16 USB port. It's a thumb drive.</p> <p>17 Q. And do you still have all</p> <p>18 those thumb drives?</p> <p>19 A. They are somewhere in my</p> <p>20 house, yes.</p> <p>21 Q. So if I requested of your</p> <p>22 counsel that we can get a copy of those,</p> <p>23 that's something you can provide to us?</p> <p>24 A. If that's what Butler Snow</p>
<p style="text-align: right;">Page 139</p> <p>1 so I have no recollection or was</p> <p>2 not provided with that</p> <p>3 information.</p> <p>4 BY MR. ZONIES:</p> <p>5 Q. That information was not</p> <p>6 provided to you in preparation for your</p> <p>7 expert report?</p> <p>8 A. If it's buried in one of</p> <p>9 those little USB ports, some of it I</p> <p>10 didn't have time to open it. I would</p> <p>11 have logged in 200 hours. So I read what</p> <p>12 I read from the background materials that</p> <p>13 they provided to me, but I don't have any</p> <p>14 independent recollection of seeing</p> <p>15 something that mentioned illegality.</p> <p>16 Q. And it sounds like there may</p> <p>17 be documents that were provided to you</p> <p>18 that may or may not be on your reliance</p> <p>19 list that you may or may not have had the</p> <p>20 opportunity to read. Is that fair?</p> <p>21 A. That would be fair to say</p> <p>22 and I obviously did not use them in order</p> <p>23 to prepare this report if I didn't see</p> <p>24 them.</p>	<p style="text-align: right;">Page 141</p> <p>1 and -- yes. But I thought they were</p> <p>2 sending you all of this. They were</p> <p>3 supposed to send you everything that they</p> <p>4 sent to me.</p> <p>5 Q. I agree.</p> <p>6 A. So if I don't know --</p> <p>7 MR. ZONIES: I'm going to go</p> <p>8 and mark as Exhibit 8.</p> <p>9 (Whereupon, the court</p> <p>10 reporter marked Exhibit 8 for</p> <p>11 identification as of this date.)</p> <p>12 BY MR. ZONIES:</p> <p>13 Q. Doctor, I've handed you</p> <p>14 what's been marked as Exhibit 8 and the</p> <p>15 ETH number on the bottom is 00860239 and</p> <p>16 it's yet another Gynecare TVT Obturator</p> <p>17 IFU. Do you see that?</p> <p>18 A. Yes, I do see that.</p> <p>19 Q. And I could tell you,</p> <p>20 Doctor, that it's been represented to me</p> <p>21 at least that this is the IFU that would</p> <p>22 have been in effect from 2005 through</p> <p>23 2008. Okay?</p> <p>24 A. And your Exhibit 2 that you</p>

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1 represented to me was an IFU with a date
2 of Ethicon 2005?

3 Q. If you look to the right on
4 that one, it's actually 2010.

5 A. 2010. Okay.

6 Q. Right. And that's why I'm
7 handing you Exhibit 8 because this is
8 actually the 2005 to 2008 IFU, at least
9 that's my understanding. Okay?

10 A. I will agree that this is
11 stamped, here it says TVT with a bunch of
12 numbers and it says 3/7/2008 at 1:37:03
13 p.m. so is that the date that it was
14 published or is it a date that it was
15 faxed to somebody? But the date on the
16 brochure here, it says 2005 trademark.

17 Q. And if you turn to the last
18 page of Exhibit 8, you'll see that the
19 adverse reaction section is actually the
20 same as the one we were looking at in
21 Exhibit 2. Is that right?

22 A. Let me just verify. That
23 would be correct.

24 Q. And so as with Exhibit 2,

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1 this IFU which we have marked as Exhibit
2 8 also does not contain a substantial
3 number of adverse risks and warnings that
4 are included in the 2015 IFU; correct?

5 A. I would agree that this
6 trademark 2005 but still Exhibit 8 is
7 different than the one that is marked
8 2015.

9 Q. And it has fewer adverse
10 reactions listed in it than does the 2015
11 IFU; correct?

12 A. That would be a correct
13 statement.

14 MR. ZONIES: Thank you,
15 Doctor. I have nothing further.
16 Appreciate your time today.

17 MS. GRAFF: You're done.

18 (Whereupon, the deposition
19 was concluded at approximately
20 4:53 p.m.)
21
22
23
24

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1 CERTIFICATION

2
3
4 I, EILEEN P. BARTH, hereby certify
5 that the testimony and proceedings in the
6 foregoing matter are contained fully and
7 accurately in the stenographic notes
8 taken by me and are a true and correct
9 transcript of the same.
10

11
12 EILEEN P. BARTH
13 Certified Shorthand
14 Reporter
15

16 The foregoing certification of this
17 transcript does not apply to any
18 reproduction of the same by any means
19 unless under the direct control and/or
20 direction of the certifying shorthand
21 reporter.
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1 LAWYER'S NOTES

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